

STABILITY REPORT

STABILITY REPORT NUMBER:

To be defined

CONDITION:

Long Term (25°C± 2°C and 60%± 5% of Relative Humidity)

PERFORMED BY:

E. GONZALEZ M

PROTOCOL NUMBER:

PD486

MANUFACTURING DATE:

14-03-17

PACKAGING DATE:

14-04-25

DATE STUDY STARTED:

14-03-17

PACKAGING:

Box containing 4 blister x 7 capsules

USGP PROCAPS - SOFGEN

PRODUCT NAME:

Vitamin D3 800 IU SGCs

CODE / LOT NUMBER:

300004904 / 1030179

API RECEIVING NUMBER:

1020053

|                                              |                                                                                                                                                                                                                  | TIME MONTHS                                                                       |                                                               |                                                              |                                                  |                                                   |                                                   |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------|---------------------------------------------------|---------------------------------------------------|
| TESTS                                        | ACCEPTANCE CRITERIA                                                                                                                                                                                              | 0                                                                                 | 3                                                             | 6                                                            | 9                                                | 12                                                | 18                                                |
| CAPSULE DESCRIPTION                          | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                             | Meets                                                         | Meets                                                        | Meets                                            | Meets                                             | Meets                                             |
| PACKAGING DESCRIPTION                        | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                | Meets                                                                             | Meets                                                         | Meets                                                        | Meets                                            | Meets                                             | Meets                                             |
| UNIFORMITY OF DOSAGE<br>(Content Uniformity) | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.5<br>100.1%, 99.1%, 98.5%, 97.8%, 98.7%, 97.0%, 98.5%, 98.2%, 100.2%, 100.1% |                                                               |                                                              |                                                  |                                                   |                                                   |
| DISINTEGRATION <sup>1</sup>                  | Maximum 30 minutes                                                                                                                                                                                               | 12, 11, 10, 10, 11, 12 minutes<br>(Dissolution time of shell)                     | 10, 10, 10, 11, 10, 11 minutes<br>(Dissolution time of shell) | 16, 16, 17, 16, 16,17 minutes<br>(Dissolution time of shell) | 6, 6, 6, 6, 6, 7minutes<br>(Disintegration test) | 8, 7, 8, 7, 7, 7 minutes<br>(Disintegration test) | 8, 8, 7, 7, 7, 7 minutes<br>(Disintegration test) |
| VALUE PEROXIDE                               | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                          | < 20 ppm                                                      | < 20 ppm                                                     | < 20 ppm                                         | < 20 ppm                                          | < 20 ppm                                          |
| ASSAY                                        | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                              | 0.3%                                                          | 0.2%                                                         | 0.2%                                             | 0.2%                                              | 0.2%                                              |
| ASSAY                                        | Vitamin D3 800 UI/cap; 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 100.7%                                                                            | 100.9%                                                        | 97.8%                                                        | 101.6%                                           | 97.1% <sup>2</sup>                                | 90.3% <sup>3</sup>                                |
| TRANSCHOLECALCIFEROL                         | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                    | ND<br>< 0.05 %                                                | ND<br>< 0.05 %                                               | ND<br>< 0.05 %                                   | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    |
| ANY OTHER INDIVIDUAL IMPURITY                | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 =0.1%                                                                    | RRT 1.17 =0.1%                                                | NC < 0.1%                                                    | ND<br>< 0.05 %                                   | ND<br>< 0.05 %                                    | RRT 1.17 =0.1%                                    |
| TOTAL IMPURITIES                             | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                              | 0.1%                                                          | 0.1%                                                         | ND<br>< 0.05 %                                   | ND<br>< 0.05 %                                    | 0.1%                                              |
| AEROBIC MICROBIAL COUNT (TAMC)               | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                        |                                                               | < 10 cfu/g                                                   |                                                  | < 10 cfu/g                                        |                                                   |
| MOLDS AND YEASTS COUNT (TYMC)                | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                        |                                                               | < 10 cfu/g                                                   |                                                  | < 10 cfu/g                                        |                                                   |
| Escherichia coli                             | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                        |                                                               | Absent /1g                                                   |                                                  | Absent /1g                                        |                                                   |
| Staphylococcus aureus                        | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                        |                                                               | Absent /1g                                                   |                                                  | Absent /1g                                        |                                                   |
| Pseudomonas aeruginosa                       | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                        |                                                               | Absent /1g                                                   |                                                  | Absent /1g                                        |                                                   |
| Salmonella spp                               | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                       |                                                               | Absent /10g                                                  |                                                  | Absent /10g                                       |                                                   |
| SAMPLING DATE (YY/MM/DD)                     |                                                                                                                                                                                                                  |                                                                                   | 14-07-01                                                      | 14-09-18                                                     | 14-12-18                                         | 15-03-18                                          | 15-09-18                                          |
| ACTUAL TEST DATE (YY/MM/DD)                  |                                                                                                                                                                                                                  | 14-04-11                                                                          | 14-07-01                                                      | 14-09-18                                                     | 14-12-23                                         | 15-03-18                                          | 15-09-30                                          |
| METHOD REVISION NUMBER                       |                                                                                                                                                                                                                  | USGP-0221-VERSION 00                                                              | USGP-0221-VERSION 00                                          | USGP-0221-VERSION 00                                         | USGP-0221-VERSION 00                             | USGP-0221-VERSION 01                              | USGP-0221-VERSION 01                              |

Footnotes: ND (Not Detectable)  
NC (Not Quantifiable)  
1. OOT-14-11-042.  
2. OOT-15-03-018.  
3. OOS-15-09-090.

PREPARED BY:

E. Gonzalez M/16-01-14

STABILITY COORDINATOR

REVIEWED BY:

P. Socarras R. Comas  
16-01-14 16-01-14

ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY:

J. Lopez  
16-01-14

QUALITY ASSURANCE

Page 1 of 1

STABILITY REPORT

STABILITY REPORT NUMBER:

To be defined

CONDITION:

Long Term (25°C± 2°C and 60%± 5% of Relative Humidity)

PERFORMED BY:

E. GONZALEZ M

PROTOCOL NUMBER:

PD486

MANUFACTURING DATE:

14-03-19

PACKAGING DATE:

14-04-24

DATE STUDY STARTED:

14-03-19

PACKAGING:

Box containing 4 blister x 7 capsules

USGP PROCAPS - SOFGEN

PRODUCT NAME:

Vitamin D3 800 IU SGCs

CODE / LOT NUMBER:

300004904 / 1030178

API RECEIVING NUMBER:

1020053

|                                              |                                                                                                                                                                                                                  | TIME MONTHS                                                                        |                                                               |                                              |                                                   |                                                   |                                                   |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------|---------------------------------------------------|---------------------------------------------------|---------------------------------------------------|
| TESTS                                        | ACCEPTANCE CRITERIA                                                                                                                                                                                              | 0                                                                                  | 3                                                             | 6                                            | 9                                                 | 12                                                | 18                                                |
| CAPSULE DESCRIPTION                          | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                              | Meets                                                         | Meets                                        | Meets                                             | Meets                                             | Meets                                             |
| PACKAGING DESCRIPTION                        | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                | Meets                                                                              | Meets                                                         | Meets                                        | Meets                                             | Meets                                             | Meets                                             |
| UNIFORMITY OF DOSAGE<br>(Content Uniformity) | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.9<br>97.5%, 99.6%, 96.8%, 98.2%, 99.2%,<br>97.2%, 98.7%, 100.6%, 98.0%, 99.2% |                                                               |                                              |                                                   |                                                   |                                                   |
| DISINTEGRATION <sup>1</sup>                  | Maximum 30 minutes                                                                                                                                                                                               | 12, 11, 11, 12, 10, 11 minutes<br>(Dissolution time of shell)                      | 10, 11, 10, 11, 10, 11 minutes<br>(Dissolution time of shell) | 8,9,8,7,8,9 minutes<br>(Disintegration time) | 8, 7, 6, 5, 5, 5 minutes<br>(Disintegration test) | 7, 7, 8, 7, 8, 7 minutes<br>(Disintegration test) | 7, 7, 8, 8, 7, 8 minutes<br>(Disintegration test) |
| VALUE PEROXIDE                               | Maximum 20 ppm                                                                                                                                                                                                   | <20 ppm                                                                            | < 20 ppm                                                      | < 20 ppm                                     | < 20 ppm                                          | < 20 ppm                                          | < 20 ppm                                          |
| ASSAY                                        | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                               | 0.3%                                                          | 0.2%                                         | 0.2%                                              | 0.3%                                              | 0.2%                                              |
| ASSAY                                        | Vitamin D3 800 UI/cap; 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 101.0%                                                                             | 100.7%                                                        | 100.3% <sup>2</sup>                          | 102.1%                                            | 97.1% <sup>3</sup>                                | 90.1% <sup>4</sup>                                |
| TRANSCHOLECALCIFEROL                         | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                     | ND<br>< 0.05 %                                                | ND<br>< 0.05 %                               | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    |
| ANY OTHER INDIVIDUAL IMPURITY                | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 =0.1%                                                                     | RRT 1.17 =0.1%                                                | RRT 1.17 =0.1%                               | ND<br>< 0.05 %                                    | RRT 1.17 =0.1%                                    | RRT 1.17 =0.1%                                    |
| TOTAL IMPURITIES                             | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                               | 0.1%                                                          | 0.1%                                         | ND<br>< 0.05 %                                    | 0.1%                                              | 0.1%                                              |
| AEROBIC MICROBIAL COUNT (TAMC)               | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                         |                                                               | < 10 cfu/g                                   |                                                   | < 10 cfu/g                                        |                                                   |
| MOLDS AND YEASTS COUNT (TYMC)                | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                         |                                                               | < 10 cfu/g                                   |                                                   | < 10 cfu/g                                        |                                                   |
| Escherichia coli                             | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                               | Absent /1g                                   |                                                   | Absent /1g                                        |                                                   |
| Staphylococcus aureus                        | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                               | Absent /1g                                   |                                                   | Absent /1g                                        |                                                   |
| Pseudomonas aeruginosa                       | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                               | Absent /1g                                   |                                                   | Absent /1g                                        |                                                   |
| Salmonella spp                               | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                        |                                                               | Absent /10g                                  |                                                   | Absent /10g                                       |                                                   |
| SAMPLING DATE (YY/MM/DD)                     |                                                                                                                                                                                                                  |                                                                                    | 14-07-01                                                      | 14-09-19                                     | 14-12-18                                          | 15-03-18                                          | 15-09-18                                          |
| ACTUAL TEST DATE (YY/MM/DD)                  |                                                                                                                                                                                                                  | 14-04-11                                                                           | 14-07-01                                                      | 14-09-25                                     | 14-12-23                                          | 15-03-18                                          | 15-09-30                                          |
| METHOD REVISION NUMBER                       |                                                                                                                                                                                                                  | USGP-0221-VERSION 00                                                               | USGP-0221-VERSION 00                                          | USGP-0221-VERSION 00                         | USGP-0221-VERSION 00                              | USGP-0221-VERSION 01                              | USGP-0221-VERSION 01                              |

Footnotes: ND (Not Detectable)

1. OOT-14-11-042.

2. OOT-14-10-033.

3. OOT-15-03-018.

4. OOS-15-09-090.

PREPARED BY: 

E. Gonzalez M/16-01-14

STABILITY COORDINATOR

REVIEWED BY: 

R. Gomez

ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: 

J. Gomez

QUALITY ASSURANCE



STABILITY REPORT

STABILITY REPORT NUMBER:  
CONDITION:  
PERFORMED BY:  
PROTOCOL NUMBER:  
  
MANUFACTURING DATE:  
PACKAGING DATE:  
DATE STUDY STARTED:  
  
PACKAGING:

To be defined  
Long Term (25°C ± 2°C and 60% ± 5% of Relative Humidity)  
E. GONZALEZ M  
PD406  
  
14-03-17  
14-04-25  
14-03-17  
  
Box containing 4 blister x 7 capsules

USGP PROCAPS - SOFGEN

PRODUCT NAME:  
CODE / LOT NUMBER:  
API RECEIVING NUMBER:

Vitamin D3 800 IU SGCs  
300004904 / 1030180  
1020053

|                                              |                                                                                                                                                                                                                  | TIME MONTHS                                                                        |                                                   |                                                               |                                                   |                                                   |                                                   |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------|---------------------------------------------------|---------------------------------------------------|
| TESTS                                        | ACCEPTANCE CRITERIA                                                                                                                                                                                              | 0                                                                                  | 3                                                 | 6                                                             | 9                                                 | 12                                                | 18                                                |
| CAPSULE DESCRIPTION                          | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                              | Meets                                             | Meets                                                         | Meets                                             | Meets                                             | Meets                                             |
| PACKAGING DESCRIPTION                        | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                | Meets                                                                              | Meets                                             | Meets                                                         | Meets                                             | Meets                                             | Meets                                             |
| UNIFORMITY OF DOSAGE<br>(Content Uniformity) | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.5<br>99.4%, 99.0%, 99.1%, 98.6%, 99.9%,<br>100.7%, 97.2%, 98.1%, 97.6%, 99.0% |                                                   |                                                               |                                                   |                                                   |                                                   |
| DISINTEGRATION <sup>1</sup>                  | Maximum 30 minutes                                                                                                                                                                                               | 11, 10, 10, 11, 11, 10 minutes<br>(Dissolution time of shell)                      | 8, 8, 9, 9, 8, 9 minutes<br>(Disintegration time) | 17, 17, 17, 17, 17, 18 minutes<br>(Dissolution time of shell) | 7, 7, 6, 6, 5, 5 minutes<br>(Disintegration Test) | 7, 7, 7, 8, 7, 7 minutes<br>(Disintegration test) | 7, 8, 8, 8, 7, 8 minutes<br>(Disintegration test) |
| VALUE PEROXIDE                               | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                           | < 20 ppm                                          | < 20 ppm                                                      | < 20 ppm                                          | < 20 ppm                                          | < 20 ppm                                          |
| ASSAY                                        | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                               | 0.2%                                              | 0.2%                                                          | 0.2%                                              | 0.2%                                              | 0.2%                                              |
| ASSAY                                        | Vitamin D3 800 UI/cap; 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 100.8%                                                                             | 101.9%                                            | 98.4% <sup>2</sup>                                            | 101.4%                                            | 96.8% <sup>3</sup>                                | 91.5% <sup>4</sup>                                |
| TRANSCHOLECALCIFEROL                         | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                     | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                                | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    |
| ANY OTHER INDIVIDUAL IMPURITY                | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 =0.1%                                                                     | RRT 1.17 =0.1%                                    | RRT 1.17 =0.1%                                                | ND<br>< 0.05 %                                    | RRT 1.17 =0.1%                                    | ND<br>< 0.05 %                                    |
| TOTAL IMPURITIES                             | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                               | 0.1%                                              | 0.1%                                                          | ND<br>< 0.05 %                                    | 0.1%                                              | ND<br>< 0.05 %                                    |
| AEROBIC MICROBIAL COUNT (TAMC)               | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                         |                                                   | < 10 cfu/g                                                    |                                                   | < 10 cfu/g                                        |                                                   |
| MOLDS AND YEASTS COUNT (TYMC)                | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                         |                                                   | < 10 cfu/g                                                    |                                                   | < 10 cfu/g                                        |                                                   |
| Escherichia coli                             | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | Absent /1g                                                    |                                                   | Absent /1g                                        |                                                   |
| Staphylococcus aureus                        | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | Absent /1g                                                    |                                                   | Absent /1g                                        |                                                   |
| Pseudomonas aeruginosa                       | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | Absent /1g                                                    |                                                   | Absent /1g                                        |                                                   |
| Salmonella spp                               | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                        |                                                   | Absent /10g                                                   |                                                   | Absent /10g                                       |                                                   |
| SAMPLING DATE (YY/MM/DD)                     |                                                                                                                                                                                                                  |                                                                                    | 14-07-01                                          | 14-09-18                                                      | 14-12-18                                          | 15-03-18                                          | 15-09-18                                          |
| ACTUAL TEST DATE (YY/MM/DD)                  |                                                                                                                                                                                                                  | 14-04-11                                                                           | 14-07-01                                          | 14-09-18                                                      | 14-12-23                                          | 15-03-18                                          | 15-09-30                                          |
| METHOD REVISION NUMBER                       |                                                                                                                                                                                                                  | USGP-0221-VERSION 00                                                               | USGP-0221-VERSION 00                              | USGP-0221-VERSION 00                                          | USGP-0221-VERSION 00                              | USGP-0221-VERSION 01                              | USGP-0221-VERSION 01                              |

Footnotes: ND (Not Detectable)  
1. OOT-14-11-042.  
2. OOT-14-09-025.  
3. OOT-15-03-018.  
4. OOS-15-09-090.

PREPARED BY: E. Gonzalez M / 16-01-14  
STABILITY COORDINATOR

REVIEWED BY: J. Sacarias R. Conner  
16-01-14 16-01-14  
ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: J. L. Gonzalez M / 16-01-14  
QUALITY ASSURANCE

Page 1 of 1

## STABILITY REPORT

| STABILITY REPORT NUMBER:                            |                                                                                                                                                                                                                  | To be defined                                                                      |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------|---------------------------------------------------|---------------------------------------------------|---------------------------------------------------|----|----|----|----|
| CONDITION:                                          |                                                                                                                                                                                                                  | Zone IVb (30°C± 2°C and 75%± 5% of Relative Humidity)                              |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| PERFORMED BY:                                       |                                                                                                                                                                                                                  | L. Barragan                                                                        |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| PROTOCOL NUMBER:                                    |                                                                                                                                                                                                                  | PD486                                                                              |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| MANUFACTURING DATE:                                 |                                                                                                                                                                                                                  | 14-03-19                                                                           |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| PACKAGING DATE:                                     |                                                                                                                                                                                                                  | 14-04-24                                                                           |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| DATE STUDY STARTED:                                 |                                                                                                                                                                                                                  | 14-05-04                                                                           |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| PACKAGING:                                          |                                                                                                                                                                                                                  | Box containing 4 blister x 7 capsules                                              |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
|                                                     |                                                                                                                                                                                                                  |                                                                                    |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
|                                                     |                                                                                                                                                                                                                  |                                                                                    |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| TESTS                                               |                                                                                                                                                                                                                  | TIME MONTHS                                                                        |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| ACCEPTANCE CRITERIA                                 |                                                                                                                                                                                                                  | 0                                                                                  | 3                                                 | 6                                                 | 9                                                 | 12                                                | 18 | 24 | 30 | 36 |
| CAPSULE DESCRIPTION                                 | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                              | Meets                                             | Meets                                             | Meets                                             | Meets                                             |    |    |    |    |
| PACKAGING DESCRIPTION                               | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                | Meets                                                                              | Meets                                             | Meets                                             | Meets                                             | Meets                                             |    |    |    |    |
| UNIFORMITY OF DOSAGE<br>(Content Uniformity)        | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.9<br>97.5%, 99.6%, 98.8%, 98.2%, 99.2%,<br>97.2%, 98.7%, 100.6%, 98.0%, 99.2% |                                                   |                                                   |                                                   |                                                   |    |    |    |    |
| DISINTEGRATION <sup>1</sup>                         | Maximum 30 minutes                                                                                                                                                                                               | 12, 11, 11, 12, 10, 11 minutes<br>(Dissolution time of shell)                      | 6, 6, 5, 7, 5, 6 minutes<br>(Disintegration time) | 5, 5, 6, 6, 6, 5 minutes<br>(Disintegration time) | 5, 6, 5, 5, 6, 6 minutes<br>(Disintegration time) | 6, 6, 5, 6, 6, 6 minutes<br>(Disintegration time) |    |    |    |    |
| VALUE PEROXIDE                                      | Maximum 20 ppm                                                                                                                                                                                                   | <20 ppm                                                                            | < 20 ppm                                          | < 20 ppm                                          | < 20 ppm                                          | < 20 ppm                                          |    |    |    |    |
| ASSAY                                               | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                               | 0.2%                                              | 0.2%                                              | 0.2%                                              | 0.2%                                              |    |    |    |    |
| ASSAY                                               | Vitamin D3 800 IU/cap; 90.0 – 115.0% (720 – 920 IU/cap.)                                                                                                                                                         | 101.0%                                                                             | 97.5%                                             | 100.4%                                            | 96.3%                                             | 95.6%                                             |    |    |    |    |
| TRANSCOLECALCIFEROL                                 | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                     | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    |    |    |    |    |
| ANY OTHER INDIVIDUAL IMPURITY                       | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 =0.1%                                                                     | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | RRT 1.17 = NC (<0.1%)                             | RRT 1.17 =0.1%                                    |    |    |    |    |
| TOTAL IMPURITIES                                    | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                               | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | NC (<0.1%)                                        | 0.1%                                              |    |    |    |    |
| AEROBIC MICROBIAL COUNT (TAMC)                      | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                         |                                                   | < 10 cfu/g                                        |                                                   | < 10 cfu/g                                        |    |    |    |    |
| MOLDS AND YEASTS COUNT (TYMC)                       | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                         |                                                   | < 10 cfu/g                                        |                                                   | < 10 cfu/g                                        |    |    |    |    |
| Escherichia coli                                    | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | 5 cfu/g                                           |                                                   | < 10 cfu/g                                        |    |    |    |    |
| Staphylococcus aureus                               | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | Absent /1g                                        |                                                   | Absent /1g                                        |    |    |    |    |
| Pseudomonas aeruginosa                              | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | Absent /1g                                        |                                                   | Absent /1g                                        |    |    |    |    |
| Salmonella spp                                      | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                        |                                                   | Absent /10g                                       |                                                   | Absent /10g                                       |    |    |    |    |
| SAMPLING DATE (YY/MM/DD)                            |                                                                                                                                                                                                                  |                                                                                    | 14-08-05                                          | 14-11-06                                          | 15-02-05                                          | 15-05-05                                          |    |    |    |    |
| ACTUAL TEST DATE (YY/MM/DD)                         |                                                                                                                                                                                                                  | 14-04-11                                                                           | 14-08-06                                          | 14-11-06                                          | 15-02-07                                          | 15-05-08                                          |    |    |    |    |
| METHOD REVISION NUMBER                              |                                                                                                                                                                                                                  | USGP-0221-VERSION 00                                                               | USGP-0221-VERSION 00                              | USGP-0221-VERSION 00                              | USGP-0221-VERSION 00                              | USGP-0221-VERSION 01                              |    |    |    |    |
| Footnotes: ND (Not Detectable)<br>1. OOT-14-11-042. |                                                                                                                                                                                                                  |                                                                                    |                                                   |                                                   |                                                   |                                                   |    |    |    |    |

PREPARED BY: J. Barragan 115-07-27  
STABILITY COORDINATOR

REVIEWED BY: S. Arcejo / R. Connor  
13-07-27 15-07-27  
ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: Mestasweda/15-07-27  
QUALITY ASSURANCE

## STABILITY REPORT

| STABILITY REPORT NUMBER:                            |                                                                                                                                                                                                                  | To be defined                                                                        |                                                |                                                   |                                                   |                                                   |    |    |    |    |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------------------|---------------------------------------------------|---------------------------------------------------|---------------------------------------------------|----|----|----|----|
| CONDITION:                                          |                                                                                                                                                                                                                  | Zone IVb (30°C± 2°C and 75%± 5% of Relative Humidity)                                |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| PERFORMED BY:                                       |                                                                                                                                                                                                                  | L. Barragan                                                                          |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| PROTOCOL NUMBER:                                    |                                                                                                                                                                                                                  | PD486                                                                                |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| MANUFACTURING DATE:                                 |                                                                                                                                                                                                                  | 14-03-17                                                                             |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| PACKAGING DATE:                                     |                                                                                                                                                                                                                  | 14-04-25                                                                             |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| DATE STUDY STARTED:                                 |                                                                                                                                                                                                                  | 14-05-04                                                                             |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| PACKAGING:                                          |                                                                                                                                                                                                                  | Box containing 4 blister x 7 capsules                                                |                                                |                                                   |                                                   |                                                   |    |    |    |    |
|                                                     |                                                                                                                                                                                                                  |                                                                                      |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| USGP PROCAPS - SOFGEN                               |                                                                                                                                                                                                                  |                                                                                      |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| PRODUCT NAME: Vitamin D3 800 IU SGCs                |                                                                                                                                                                                                                  |                                                                                      |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| CODE / LOT NUMBER: 300004904 / 1030179              |                                                                                                                                                                                                                  |                                                                                      |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| API RECEIVING NUMBER: 1020053                       |                                                                                                                                                                                                                  |                                                                                      |                                                |                                                   |                                                   |                                                   |    |    |    |    |
|                                                     |                                                                                                                                                                                                                  |                                                                                      |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| TESTS                                               |                                                                                                                                                                                                                  | TIME MONTHS                                                                          |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| ACCEPTANCE CRITERIA                                 |                                                                                                                                                                                                                  | 0                                                                                    | 3                                              | 6                                                 | 9                                                 | 12                                                | 18 | 24 | 30 | 36 |
| CAPSULE DESCRIPTION                                 | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                                | Meets                                          | Meets                                             | Meets                                             | Meets                                             |    |    |    |    |
| PACKAGING DESCRIPTION                               | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                | Meets                                                                                | Meets                                          | Meets                                             | Meets                                             | Meets                                             |    |    |    |    |
| UNIFORMITY OF DOSAGE<br>(Content Uniformity)        | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.5<br>100.1%, 99.1%, 98.5%, 97.8%, 98.7%,<br>97.0%, 98.5%, 98.2%, 100.2%, 100.1% |                                                |                                                   |                                                   |                                                   |    |    |    |    |
| DISINTEGRATION¹                                     | Maximum 30 minutes                                                                                                                                                                                               | 12, 11, 10, 10, 11, 12 minutes<br>(Dissolution time of shell)                        | 5, 6, 6, 6, 6 minutes<br>(Disintegration time) | 5, 5, 5, 6, 6, 5 minutes<br>(Disintegration time) | 6, 6, 6, 6, 6, 5 minutes<br>(Disintegration time) | 6, 6, 5, 5, 6, 6 minutes<br>(Disintegration time) |    |    |    |    |
| VALUE PEROXIDE                                      | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                             | < 20 ppm                                       | < 20 ppm                                          | < 20 ppm                                          | < 20 ppm                                          |    |    |    |    |
| ASSAY                                               | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                                 | 0.2%                                           | 0.2%                                              | 0.2%                                              | 0.2%                                              |    |    |    |    |
| ASSAY                                               | Vitamin D3 800 UI/cap; 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 100.7%                                                                               | 98.3%                                          | 103.7%                                            | 98.0%                                             | 94.6%                                             |    |    |    |    |
| TRANSCHOLECALCIFEROL                                | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                       | ND<br>< 0.05 %                                 | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    |    |    |    |    |
| ANY OTHER INDIVIDUAL IMPURITY                       | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 =0.1%                                                                       | ND<br>< 0.05 %                                 | ND<br>< 0.05 %                                    | RRT 1.17 =0.1%                                    | RRT 1.17 =0.1%                                    |    |    |    |    |
| TOTAL IMPURITIES                                    | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                                 | ND<br>< 0.05 %                                 | ND<br>< 0.05 %                                    | 0.1%                                              | 0.1%                                              |    |    |    |    |
| AEROBIC MICROBIAL COUNT (TAMC)                      | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                           |                                                | < 10 cfu/g                                        |                                                   | < 10 cfu/g                                        |    |    |    |    |
| MOLDS AND YEASTS COUNT (TYMC)                       | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                           |                                                | < 10 cfu/g                                        |                                                   | < 10 cfu/g                                        |    |    |    |    |
| Escherichia coli                                    | Absent /1g                                                                                                                                                                                                       |                                                                                      |                                                | Absent /1g                                        |                                                   | Absent /1g                                        |    |    |    |    |
| Staphylococcus aureus                               | Absent /1g                                                                                                                                                                                                       |                                                                                      |                                                | Absent /1g                                        |                                                   | Absent /1g                                        |    |    |    |    |
| Pseudomonas aeruginosa                              | Absent /1g                                                                                                                                                                                                       |                                                                                      |                                                | Absent /1g                                        |                                                   | Absent /1g                                        |    |    |    |    |
| Salmonella spp                                      | Absent /10g                                                                                                                                                                                                      |                                                                                      |                                                | Absent /10g                                       |                                                   | Absent /10g                                       |    |    |    |    |
| SAMPLING DATE (YY/MM/DD)                            |                                                                                                                                                                                                                  |                                                                                      | 14-08-05                                       | 14-11-06                                          | 15-02-05                                          | 15-05-05                                          |    |    |    |    |
| ACTUAL TEST DATE (YYMM/DD)                          |                                                                                                                                                                                                                  | 14-04-11                                                                             | 14-08-06                                       | 14-11-06                                          | 15-02-07                                          | 15-05-08                                          |    |    |    |    |
| METHOD REVISION NUMBER                              |                                                                                                                                                                                                                  | USGP-Q221-VERSION 00                                                                 | USGP-Q221-VERSION 00                           | USGP-Q221-VERSION 00                              | USGP-Q221-VERSION 00                              | USGP-Q221-VERSION 01                              |    |    |    |    |
| Footnotes: ND (Not Detectable)<br>1. OOT-14-11-042. |                                                                                                                                                                                                                  |                                                                                      |                                                |                                                   |                                                   |                                                   |    |    |    |    |

PREPARED BY: J. Barragán / 15-07-27  
STABILITY COORDINATOR

REVIEWED BY: S. Araujo / R. Connors  
13-01-27 15-01-27  
 ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: Alastair edo/19-07-28  
QUALITY ASSURANCE

## STABILITY REPORT

| STABILITY REPORT NUMBER:                            |                                                                                                                                                                                                                  | To be defined                                                                      |                                                   |                                                   |                                                |                                                |    |    |    |    |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------|---------------------------------------------------|------------------------------------------------|------------------------------------------------|----|----|----|----|
| CONDITION:                                          |                                                                                                                                                                                                                  | Zone IVb (30°C± 2°C and 75%± 5% of Relative Humidity)                              |                                                   |                                                   |                                                |                                                |    |    |    |    |
| PERFORMED BY:                                       |                                                                                                                                                                                                                  | L. Barragán                                                                        |                                                   |                                                   |                                                |                                                |    |    |    |    |
| PROTOCOL NUMBER:                                    |                                                                                                                                                                                                                  | PD466                                                                              |                                                   |                                                   |                                                |                                                |    |    |    |    |
| MANUFACTURING DATE:                                 |                                                                                                                                                                                                                  | 14-03-17                                                                           |                                                   |                                                   |                                                |                                                |    |    |    |    |
| PACKAGING DATE:                                     |                                                                                                                                                                                                                  | 14-04-25                                                                           |                                                   |                                                   |                                                |                                                |    |    |    |    |
| DATE STUDY STARTED:                                 |                                                                                                                                                                                                                  | 14-05-04                                                                           |                                                   |                                                   |                                                |                                                |    |    |    |    |
| PACKAGING:                                          |                                                                                                                                                                                                                  | Box containing 4 blister x 7 capsules                                              |                                                   |                                                   |                                                |                                                |    |    |    |    |
|                                                     |                                                                                                                                                                                                                  |                                                                                    |                                                   |                                                   |                                                |                                                |    |    |    |    |
|                                                     |                                                                                                                                                                                                                  |                                                                                    |                                                   |                                                   |                                                |                                                |    |    |    |    |
| TESTS                                               |                                                                                                                                                                                                                  | TIME MONTHS                                                                        |                                                   |                                                   |                                                |                                                |    |    |    |    |
| ACCEPTANCE CRITERIA                                 |                                                                                                                                                                                                                  | 0                                                                                  | 3                                                 | 6                                                 | 9                                              | 12                                             | 18 | 24 | 30 | 36 |
| CAPSULE DESCRIPTION                                 | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                              | Meets                                             | Meets                                             | Meets                                          | Meets                                          |    |    |    |    |
| PACKAGING DESCRIPTION                               | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                | Meets                                                                              | Meets                                             | Meets                                             | Meets                                          | Meets                                          |    |    |    |    |
| UNIFORMITY OF DOSAGE<br>(Content Uniformity)        | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.5<br>99.4%, 99.0%, 99.1%, 98.6%, 99.8%,<br>100.7%, 97.2%, 98.1%, 97.6%, 99.0% |                                                   |                                                   |                                                |                                                |    |    |    |    |
| DISINTEGRATION¹                                     | Maximum 30 minutes                                                                                                                                                                                               | 11, 10, 10, 11, 11, 10 minutes<br>(Dissolution time of shell)                      | 6, 5, 4, 6, 5, 6 minutes<br>(Disintegration time) | 6, 6, 5, 5, 6, 5 minutes<br>(Disintegration time) | 6, 6, 5, 5, 6 minutes<br>(Disintegration time) | 6, 6, 6, 6, 6 minutes<br>(Disintegration time) |    |    |    |    |
| VALUE PEROXIDE                                      | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                           | < 20 ppm                                          | < 20 ppm                                          | < 20 ppm                                       | < 20 ppm                                       |    |    |    |    |
| ASSAY                                               | Vitamin E. Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                               | 0.2%                                              | 0.2%                                              | 0.2%                                           | 0.2%                                           |    |    |    |    |
| ASSAY                                               | Vitamin D3 800 UI/cap; 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 100.6%                                                                             | 98.9%                                             | 100.7%                                            | 97.8%                                          | 95.2%                                          |    |    |    |    |
| TRANSCOLECALCIFEROL                                 | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                     | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                 | ND<br>< 0.05 %                                 |    |    |    |    |
| ANY OTHER INDIVIDUAL IMPURITY                       | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 =0.1%                                                                     | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | RRT 1.17 =0.1%                                 | RRT 1.17 =0.1%                                 |    |    |    |    |
| TOTAL IMPURITIES                                    | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                               | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                    | 0.1%                                           | 0.1%                                           |    |    |    |    |
| AEROBIC MICROBIAL COUNT (TAMC)                      | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                         |                                                   | < 10 cfu/g                                        |                                                | < 10 cfu/g                                     |    |    |    |    |
| MOLDS AND YEASTS COUNT (TYMC)                       | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                         |                                                   | < 10 cfu/g                                        |                                                | < 10 cfu/g                                     |    |    |    |    |
| Escherichia coli                                    | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | Absent /1g                                        |                                                | Absent /1g                                     |    |    |    |    |
| Staphylococcus aureus                               | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | Absent /1g                                        |                                                | Absent /1g                                     |    |    |    |    |
| Pseudomonas aeruginosa                              | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |                                                   | Absent /1g                                        |                                                | Absent /1g                                     |    |    |    |    |
| Salmonella spp                                      | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                        |                                                   | Absent /10g                                       |                                                | Absent /10g                                    |    |    |    |    |
| SAMPLING DATE (YY/MM/DD)                            |                                                                                                                                                                                                                  |                                                                                    | 14-08-05                                          | 14-11-06                                          | 15-02-05                                       | 15-05-05                                       |    |    |    |    |
| ACTUAL TEST DATE (YYMM/DD)                          |                                                                                                                                                                                                                  | 14-04-11                                                                           | 14-08-06                                          | 14-11-06                                          | 15-02-07                                       | 15-05-08                                       |    |    |    |    |
| METHOD REVISION NUMBER                              |                                                                                                                                                                                                                  | USGP-0221-VERSION 00                                                               | USGP-0221-VERSION 00                              | USGP-0221-VERSION 00                              | USGP-0221-VERSION 00                           | USGP-0221-VERSION 01                           |    |    |    |    |
| Footnotes: ND (Not Detectable)<br>1. OOT-14-11-042. |                                                                                                                                                                                                                  |                                                                                    |                                                   |                                                   |                                                |                                                |    |    |    |    |

PREPARED BY: L. Barragan 15-07-27  
STABILITY COORDINATOR

REVIEWED BY: S. Arora / RCemon  
15-07-27 / 15-07-27  
 ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: Alastair/15-07-27  
QUALITY ASSURANCE

## STABILITY REPORT

|                                                                                                                                                                      |  |                                                                                                                 |  |  |  |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------|--|--|--|--|
| STABILITY REPORT NUMBER: To be defined<br>CONDITION: Accelerated (40°C± 2°C and 75%± 5% of Relative Humidity)<br>PERFORMED BY: L. Barragán<br>PROTOCOL NUMBER: PD486 |  | <b>USGP PROCAPS - SOFGEN</b>                                                                                    |  |  |  |  |
| MANUFACTURING DATE: 14-03-19<br>PACKAGING DATE: 14-04-24<br>DATE STUDY STARTED: 14-04-29<br>PACKAGING: Box containing 4 blister x 7 capsules                         |  | PRODUCT NAME: Vitamin D3 800 IU SGCs<br>CODE / LOT NUMBER: 300004904 / 1030178<br>API RECEIVING NUMBER: 1020053 |  |  |  |  |

  

| TESTS                                     | ACCEPTANCE CRITERIA                                                                                                                                                                                              | TIME MONTHS                                                                     |                                                            |   |                                                |                                                |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------------------------------------------|---|------------------------------------------------|------------------------------------------------|
|                                           |                                                                                                                                                                                                                  | 0                                                                               | 1                                                          | 2 | 3                                              | 6                                              |
| CAPSULE DESCRIPTION                       | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                           | Meets                                                      |   | Meets                                          | Meets                                          |
| PACKAGING DESCRIPTION                     | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                |                                                                                 | Meets                                                      |   | Meets                                          | Meets                                          |
| UNIFORMITY OF DOSAGE (Content Uniformity) | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.9<br>97.5%, 99.6%, 96.8%, 98.2%, 99.2%, 97.2%, 98.7%, 100.6%, 98.0%, 99.2% |                                                            |   |                                                |                                                |
| DISINTEGRATION <sup>1</sup>               | Maximum 30 minutes                                                                                                                                                                                               | 12, 11, 11, 12, 10, 11 minutes (Dissolution time of shell)                      | 11, 11, 10, 12, 10, 13 minutes (Dissolution time of shell) |   | 6, 7, 7, 6, 6, 7 minutes (Disintegration Time) | 8, 9, 9, 8, 9, 8 minutes (Disintegration Time) |
| VALUE PEROXIDE                            | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                        | < 20 ppm                                                   |   | < 20 ppm                                       | < 20 ppm                                       |
| ASSAY                                     | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                            | 0.2%                                                       |   | 0.2%                                           | 0.2%                                           |
| ASSAY                                     | Vitamin D3 800 UI/cap: 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 101.0%                                                                          | 98.4% <sup>2</sup>                                         |   | 97.0%                                          | 97.4%                                          |
| TRANSCHOLECALCIFEROL                      | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                  | ND<br>< 0.05 %                                             |   | ND<br>< 0.05 %                                 | ND<br>< 0.05 %                                 |
| ANY OTHER INDIVIDUAL IMPURITY             | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 = 0.1%                                                                 | RRT 1.17 = 0.1%                                            |   | RRT 1.17 = 0.1%<br>RRT 1.23 = 0.1 %            | RRT 1.07 = 0.2 %                               |
| TOTAL IMPURITIES                          | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                            | 0.1%                                                       |   | 0.2%                                           | 0.2%                                           |
| AEROBIC MICROBIAL COUNT (TAMC)            | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                      |                                                            |   | < 10 cfu/g                                     |                                                |
| MOLDS AND YEASTS COUNT (TYMC)             | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                      |                                                            |   | < 10 cfu/g                                     |                                                |
| Escherichia coli                          | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                      |                                                            |   | Absent /1g                                     |                                                |
| Staphylococcus aureus                     | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                      |                                                            |   | Absent /1g                                     |                                                |
| Pseudomonas aeruginosa                    | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                      |                                                            |   | Absent /1g                                     |                                                |
| Salmonella spp                            | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                     |                                                            |   | Absent /10g                                    |                                                |
| SAMPLING DATE (YY/MM/DD)                  |                                                                                                                                                                                                                  |                                                                                 | 14-05-30                                                   |   | 14-07-30                                       | 2014-10-30                                     |
| ACTUAL TEST DATE (YY/MM/DD)               |                                                                                                                                                                                                                  | 14-04-11                                                                        | 14-05-30                                                   |   | 14-07-31                                       | 2014-11-01                                     |
| METHOD REVISION NUMBER                    |                                                                                                                                                                                                                  | USGP-0221-VERSION 00                                                            | USGP-0221-VERSION 00                                       |   | USGP-0221-VERSION 00                           | USGP-0221-VERSION 00                           |

Footnotes: ND (Not Detectable).  
 1. OOT-14-11-042.  
 2. US-14-06-042

PREPARED BY: P. L. S. Barragán / 15-01-29  
 STABILITY COORDINATOR

REVIEWED BY: S. Arayo / R. Cernadas  
15-01-29 / 15-01-29  
 ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: [Signature] / 15-01-29  
 QUALITY ASSURANCE



## STABILITY REPORT

|                                                                                                                                                                                                                                                                                                                      |  |                                                                                                                                                     |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------|--|
| STABILITY REPORT NUMBER: To be defined<br>CONDITION: Accelerated (40°C± 2°C and 75%± 5% of Relative Humidity)<br>PERFORMED BY: L. Barragán<br>PROTOCOL NUMBER: PD486<br>MANUFACTURING DATE: 14-03-17<br>PACKAGING DATE: 14-04-25<br>DATE STUDY STARTED: 14-04-29<br>PACKAGING: Box containing 4 blister x 7 capsules |  | <b>USGP PROCAPS - SOFGEN</b><br><br>PRODUCT NAME: Vitamin D3 800 IU SGCs<br>CODE / LOT NUMBER: 300004804 / 1030179<br>API RECEIVING NUMBER: 1020053 |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------|--|

  

|                                              |                                                                                                                                                                                                                  | TIME MONTHS                                                                          |                                                               |   |                                                   |                                                |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------|---|---------------------------------------------------|------------------------------------------------|
| TESTS                                        | ACCEPTANCE CRITERIA                                                                                                                                                                                              | 0                                                                                    | 1                                                             | 2 | 3                                                 | 6                                              |
| CAPSULE DESCRIPTION                          | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                                | Meets                                                         |   | Meets                                             | Meets                                          |
| PACKAGING DESCRIPTION                        | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                |                                                                                      | Meets                                                         |   | Meets                                             | Meets                                          |
| UNIFORMITY OF DOSAGE<br>(Content Uniformity) | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.5<br>100.1%, 99.1%, 98.5%, 97.8%, 98.7%,<br>97.0%, 98.5%, 98.2%, 100.2%, 100.1% |                                                               |   |                                                   |                                                |
| DISINTEGRATION <sup>1</sup>                  | Maximum 30 minutes                                                                                                                                                                                               | 12, 11, 10, 10, 11, 12 minutes<br>(Dissolution time of shell)                        | 13, 12, 13, 12, 13, 13 minutes<br>(Dissolution time of shell) |   | 8, 7, 7, 6, 7, 8 minutes<br>(Disintegration Time) | 8, 9, 9, 8, 8 minutes<br>(Disintegration Time) |
| VALUE PEROXIDE                               | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                             | < 20 ppm                                                      |   | < 20 ppm                                          | < 20 ppm                                       |
| ASSAY                                        | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                                 | 0.2%                                                          |   | 0.2%                                              | 0.2%                                           |
| ASSAY                                        | Vitamin D3 800 UI/cap: 90.0 – 115.0%<br>(720 – 920 UI/cap.)                                                                                                                                                      | 100.7%                                                                               | 98.5%                                                         |   | 97.1%                                             | 97.0%                                          |
| TRANSCHOLECALCIFEROL                         | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                       | ND<br>< 0.05 %                                                |   | ND<br>< 0.05 %                                    | ND<br>< 0.05 %                                 |
| ANY OTHER INDIVIDUAL IMPURITY                | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 =0.1%                                                                       | RRT 1.17 =0.1%                                                |   | RRT 1.17 =0.1%<br>RRT 1.23 = 0.1 %                | RRT 1.07 =0.2%                                 |
| TOTAL IMPURITIES                             | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                                 | 0.1%                                                          |   | 0.2%                                              | 0.2%                                           |
| AEROBIC MICROBIAL COUNT (TAMC)               | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                           |                                                               |   | < 10 cfu/g                                        |                                                |
| MOLDS AND YEASTS COUNT (TYMC)                | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                           |                                                               |   | < 10 cfu/g                                        |                                                |
| Escherichia coli                             | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                           |                                                               |   | Absent /1g                                        |                                                |
| Staphylococcus aureus                        | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                           |                                                               |   | Absent /1g                                        |                                                |
| Pseudomonas aeruginosa                       | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                           |                                                               |   | Absent /1g                                        |                                                |
| Salmonella spp                               | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                          |                                                               |   | Absent /10g                                       |                                                |
| SAMPLING DATE (YY/MM/DD)                     |                                                                                                                                                                                                                  |                                                                                      | 14-05-30                                                      |   | 14-07-30                                          | 2014-10-30                                     |
| ACTUAL TEST DATE (YY/MM/DD)                  |                                                                                                                                                                                                                  | 14-04-11                                                                             | 14-05-30                                                      |   | 14-07-31                                          | 2014-11-01                                     |
| METHOD REVISION NUMBER                       |                                                                                                                                                                                                                  | USGP-0221-VERSION 00                                                                 | USGP-0221-VERSION 00                                          |   | USGP-0221-VERSION 00                              | USGP-0221-VERSION 00                           |

Footnotes: ND (Not Detectable).  
1. OOT-14-11-042.

PREPARED BY: L. Barragán / 15-01-29  
STABILITY COORDINATOR

REVIEWED BY: S. Arayo / R. Carrero  
15-01-29  
ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: [Signature] / 15-01-29  
QUALITY ASSURANCE



# STABILITY REPORT

| STABILITY REPORT NUMBER: To be defined<br>CONDITION: Accelerated (40°C ± 2°C and 75% ± 5% of Relative Humidity)<br>PERFORMED BY: L. Barragán<br>PROTOCOL NUMBER: PD486<br>MANUFACTURING DATE: 14-03-17<br>PACKAGING DATE: 14-04-25<br>DATE STUDY STARTED: 14-04-29<br>PACKAGING: Box containing 4 blister x 7 capsules |                                                                                                                                                                                                                  | <b>USGP PROCAPS - SOFGEN</b><br>PRODUCT NAME: Vitamin D3 800 IU SGCs<br>CODE / LOT NUMBER: 300004904 / 1030180<br>API RECEIVING NUMBER: 1020053 |                                                            |   |                                                |                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|---|------------------------------------------------|---------------------------------------------|
| TESTS                                                                                                                                                                                                                                                                                                                  | ACCEPTANCE CRITERIA                                                                                                                                                                                              | TIME MONTHS                                                                                                                                     |                                                            |   |                                                |                                             |
|                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                  | 0                                                                                                                                               | 1                                                          | 2 | 3                                              | 6                                           |
| CAPSULE DESCRIPTION                                                                                                                                                                                                                                                                                                    | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                                                                                           | Meets                                                      |   | Meets                                          | Meets                                       |
| PACKAGING DESCRIPTION                                                                                                                                                                                                                                                                                                  | Box containing 4 blister, 7 capsules / card, made of foil aluminum and film PVDC.                                                                                                                                |                                                                                                                                                 | Meets                                                      |   | Meets                                          | Meets                                       |
| UNIFORMITY OF DOSAGE (Content Uniformity)                                                                                                                                                                                                                                                                              | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV=2.5<br>99.4%, 99.0%, 99.1%, 98.6%, 99.9%, 100.7%, 97.2%, 98.1%, 97.6%, 99.0%                                                                 |                                                            |   |                                                |                                             |
| DISINTEGRATION <sup>1</sup>                                                                                                                                                                                                                                                                                            | Maximum 30 minutes                                                                                                                                                                                               | 11, 10, 10, 11, 11, 10 minutes (Dissolution time of shell)                                                                                      | 10, 12, 12, 11, 10, 10 minutes (Dissolution time of shell) |   | 7, 6, 7, 8, 7, 7 minutes (Disintegration Time) | 8, 8, 9, 8, 9 minutes (Disintegration Time) |
| VALUE PEROXIDE                                                                                                                                                                                                                                                                                                         | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                                                                                        | < 20 ppm                                                   |   | < 20 ppm                                       | < 20 ppm                                    |
| ASSAY                                                                                                                                                                                                                                                                                                                  | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                                                                                            | 0.2%                                                       |   | 0.2%                                           | 0.2%                                        |
| ASSAY                                                                                                                                                                                                                                                                                                                  | Vitamin D3 800 IU/cap; 90.0 – 115.0% (720 – 920 IU/cap.)                                                                                                                                                         | 100.6%                                                                                                                                          | 98.7% <sup>2</sup>                                         |   | 97.9%                                          | 98.0%                                       |
| TRANSCHELECALCIFEROL                                                                                                                                                                                                                                                                                                   | Maximum 1.5%                                                                                                                                                                                                     | ND<br>< 0.05 %                                                                                                                                  | ND<br>< 0.05 %                                             |   | ND<br>< 0.05 %                                 | ND<br>< 0.05 %                              |
| ANY OTHER INDIVIDUAL IMPURITY                                                                                                                                                                                                                                                                                          | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17 = 0.1%                                                                                                                                 | RRT 1.17 = 0.1%                                            |   | RRT 1.17 = 0.1%<br>RRT 1.23 = 0.1 %            | RRT 1.07 = 0.1%                             |
| TOTAL IMPURITIES                                                                                                                                                                                                                                                                                                       | Maximum 2.0%                                                                                                                                                                                                     | 0.1%                                                                                                                                            | 0.1%                                                       |   | 0.2%                                           | 0.1%                                        |
| AEROBIC MICROBIAL COUNT (TAMC)                                                                                                                                                                                                                                                                                         | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                                                                                      |                                                            |   | < 10 cfu/g                                     |                                             |
| MOLDS AND YEASTS COUNT (TYMC)                                                                                                                                                                                                                                                                                          | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                                                                                      |                                                            |   | < 10 cfu/g                                     |                                             |
| Escherichia coli                                                                                                                                                                                                                                                                                                       | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                                                                                      |                                                            |   | Absent /1g                                     |                                             |
| Staphylococcus aureus                                                                                                                                                                                                                                                                                                  | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                                                                                      |                                                            |   | Absent /1g                                     |                                             |
| Pseudomonas aeruginosa                                                                                                                                                                                                                                                                                                 | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                                                                                      |                                                            |   | Absent /1g                                     |                                             |
| Salmonella spp                                                                                                                                                                                                                                                                                                         | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                                                                                     |                                                            |   | Absent /10g                                    |                                             |
| SAMPLING DATE (YY/MM/DD)                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                  |                                                                                                                                                 | 14-05-30                                                   |   | 14-07-30                                       | 2014-10-30                                  |
| ACTUAL TEST DATE (YY/MM/DD)                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                  | 14-04-11                                                                                                                                        | 14-05-30                                                   |   | 14-07-31                                       | 2014-11-01                                  |
| METHOD REVISION NUMBER                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                  | USGP-0221-VERSION 00                                                                                                                            | USGP-0221-VERSION 00                                       |   | USGP-0221-VERSION 00                           | USGP-0221-VERSION 00                        |

Footnotes: ND (Not Detectable).  
 1. OOT-14-11-042.  
 2. US-14-06-42.

PREPARED BY: P.L.S. Barragán / 15-01-29  
 STABILITY COORDINATOR

REVIEWED BY: S. Araya / 15-01-29 | R. Comas / 15-01-29  
 ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: [Signature] / 15-01-29  
 QUALITY ASSURANCE

STABILITY REPORT

|                                                                            |                                                                                                                                                                                                                  |                                                                                    |   |   |                                                                |                                           |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---|---|----------------------------------------------------------------|-------------------------------------------|
| STABILITY REPORT NUMBER: To be defined                                     |                                                                                                                                                                                                                  | USGP PROCAPS - SOFGEN                                                              |   |   |                                                                |                                           |
| CONDITION: Holding Time (14°C To 28°C and 70%of Relative Humidity Maximum) |                                                                                                                                                                                                                  |                                                                                    |   |   |                                                                |                                           |
| PERFORMED BY: L. Barragán                                                  |                                                                                                                                                                                                                  |                                                                                    |   |   |                                                                |                                           |
| PROTOCOL NUMBER: PD480                                                     |                                                                                                                                                                                                                  |                                                                                    |   |   |                                                                |                                           |
| MANUFACTURING DATE: 14-03-17                                               |                                                                                                                                                                                                                  | PRODUCT NAME: Vitamin D3 800 IU SGCs                                               |   |   |                                                                |                                           |
| PACKAGING DATE: 14-03-31                                                   |                                                                                                                                                                                                                  | CODE / LOT NUMBER: 400004764 / 1026327                                             |   |   |                                                                |                                           |
| DATE STUDY STARTED: 14-04-09                                               |                                                                                                                                                                                                                  | API RECEIVING NUMBER: 1020053                                                      |   |   |                                                                |                                           |
| PACKAGING: Polyethylene dark bags x 100 capsules                           |                                                                                                                                                                                                                  |                                                                                    |   |   |                                                                |                                           |
|                                                                            |                                                                                                                                                                                                                  |                                                                                    |   |   |                                                                |                                           |
|                                                                            |                                                                                                                                                                                                                  | TIME MONTHS                                                                        |   |   |                                                                |                                           |
| TESTS                                                                      | ACCEPTANCE CRITERIA                                                                                                                                                                                              | 0                                                                                  | 1 | 2 | 3                                                              | 6                                         |
| CAPSULE DESCRIPTION                                                        | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                              |   |   | Meets                                                          | Meets                                     |
| PACKAGING DESCRIPTION                                                      | Polyethylene dark bag x 100 capsules.                                                                                                                                                                            | Meets                                                                              |   |   | Meets                                                          | Meets                                     |
| UNIFORMITY OF DOSAGE (Content Uniformity)                                  | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV= 2.5<br>100.1%, 99.1%, 98.5%, 97.8%, 98.7%, 97.0%, 98.5%, 98.2%, 100.2%, 100.1% |   |   |                                                                |                                           |
| DISINTEGRATION¹                                                            | Maximum 30 minutes                                                                                                                                                                                               | 12, 11, 10, 10, 11, 12 minutes (dissolution time of the shell)                     |   |   | 13, 11, 12, 11, 12, 10 minutes (dissolution time of the shell) | 6, 6, 6, 7, 6, 7 minutes (disintegration) |
| VALUE PEROXIDE                                                             | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                           |   |   | < 20 ppm                                                       | < 20 ppm                                  |
| ASSAY                                                                      | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                               |   |   | 0.2%                                                           | 0.2%                                      |
| ASSAY                                                                      | Vitamin D3 800 UI/cap; 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 100.7%                                                                             |   |   | 101.9%                                                         | 104.0%                                    |
| TRANSCHOLECALCIFEROL                                                       | Maximum 1.5%                                                                                                                                                                                                     | ND (<0.05%)                                                                        |   |   | ND (<0.05%)                                                    | ND (<0.05%)                               |
| ANY OTHER INDIVIDUAL IMPURITY                                              | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17= 0.1%                                                                     |   |   | ND (<0.05%)                                                    | ND (<0.05%)                               |
| TOTAL IMPURITIES                                                           | Maximum 2.0%                                                                                                                                                                                                     | 0.1%²                                                                              |   |   | ND (<0.05%)²                                                   | ND (<0.05%)                               |
| AEROBIC MICROBIAL COUNT (TAMC)                                             | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                         |   |   | < 10 cfu/g                                                     | < 10 cfu/g                                |
| MOLDS AND YEASTS COUNT (TYMC)                                              | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                         |   |   | < 10 cfu/g                                                     | < 10 cfu/g                                |
| Escherichia coli                                                           | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |   |   | Absent /1g                                                     | Absent /1g                                |
| Staphylococcus aureus                                                      | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |   |   | Absent /1g                                                     | Absent /1g                                |
| Pseudomonas aeruginosa                                                     | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                         |   |   | Absent /1g                                                     | Absent /1g                                |
| Salmonella spp                                                             | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                        |   |   | Absent /10g                                                    | Absent /10g                               |
| SAMPLING DATE (YY/MM/DD)                                                   |                                                                                                                                                                                                                  | Not Applied                                                                        |   |   | 14-07-09                                                       | 14-10-09                                  |
| ACTUAL TEST DATE (YY/MM/DD)                                                |                                                                                                                                                                                                                  | 14-04-11                                                                           |   |   | 14-07-10                                                       | 14-10-11                                  |
| METHOD REVISION NUMBER                                                     |                                                                                                                                                                                                                  | USGP-0221-Version 00                                                               |   |   | USGP-0221-Version 00                                           | USGP-0221-Version 00                      |
| Footnotes: ND (Not Detectable)<br>1. OOT-14-11-042.<br>2. OOT-14-08-002.   |                                                                                                                                                                                                                  |                                                                                    |   |   |                                                                |                                           |

PREPARED BY: P. L. Barragán 15-01-29  
STABILITY COORDINATOR

REVIEWED BY: S. Araya 15-01-29 R. Comas 15-01-29  
ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: H. G. [Signature] 15-01-29  
QUALITY ASSURANCE

STABILITY REPORT

|                                                                            |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                              |                                           |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---|---|--------------------------------------------------------------|-------------------------------------------|
| STABILITY REPORT NUMBER: To be defined                                     |                                                                                                                                                                                                                  | USGP PROCAPS - SOFGEN                                                            |   |   |                                                              |                                           |
| CONDITION: Holding Time (14°C To 28°C and 70%of Relative Humidity Maximum) |                                                                                                                                                                                                                  | PRODUCT NAME: Vitamin D3 800 IU SGCs                                             |   |   |                                                              |                                           |
| PERFORMED BY: L. Barragán                                                  |                                                                                                                                                                                                                  | CODE / LOT NUMBER: 400004764 / 1026328                                           |   |   |                                                              |                                           |
| PROTOCOL NUMBER: PD480                                                     |                                                                                                                                                                                                                  | API RECEIVING NUMBER: 1020053                                                    |   |   |                                                              |                                           |
| MANUFACTURING DATE: 14-03-17                                               |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                              |                                           |
| PACKAGING DATE: 14-04-04                                                   |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                              |                                           |
| DATE STUDY STARTED: 14-04-09                                               |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                              |                                           |
| PACKAGING: Polyethylene dark bags x 100 capsules                           |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                              |                                           |
|                                                                            |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                              |                                           |
|                                                                            |                                                                                                                                                                                                                  | TIME MONTHS                                                                      |   |   |                                                              |                                           |
| TESTS                                                                      | ACCEPTANCE CRITERIA                                                                                                                                                                                              | 0                                                                                | 1 | 2 | 3                                                            | 6                                         |
| CAPSULE DESCRIPTION                                                        | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                            |   |   | Meets                                                        | Meets                                     |
| PACKAGING DESCRIPTION                                                      | Polyethylene dark bag x 100 capsules.                                                                                                                                                                            | Meets                                                                            |   |   | Meets                                                        | Meets                                     |
| UNIFORMITY OF DOSAGE (Content Uniformity)                                  | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV= 2.5<br>99.4%, 99.0%, 99.1%, 98.6%, 99.9%, 100.7%, 97.2%, 98.1%, 97.6%, 99.0% |   |   |                                                              |                                           |
| DISINTEGRATION¹                                                            | Maximum 30 minutes                                                                                                                                                                                               | 11, 10, 10, 11, 11, 10 minutes (dissolution time of the shell)                   |   |   | 9, 10, 11, 11, 12, 9 minutes (dissolution time of the shell) | 6, 6, 7, 6, 7, 6 minutes (disintegration) |
| VALUE PEROXIDE                                                             | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                         |   |   | < 20 ppm                                                     | < 20 ppm                                  |
| ASSAY                                                                      | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                             |   |   | 0.2%                                                         | 0.2%                                      |
| ASSAY                                                                      | Vitamin D3 800 UI/cap; 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 100.6%                                                                           |   |   | 102.0%                                                       | 103.5%                                    |
| TRANSCHOLECALCIFEROL                                                       | Maximum 1.5%                                                                                                                                                                                                     | ND (<0.05%)                                                                      |   |   | ND (<0.05%)                                                  | ND (<0.05%)                               |
| ANY OTHER INDIVIDUAL IMPURITY                                              | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17= 0.1%                                                                   |   |   | ND (<0.05%)                                                  | ND (<0.05%)                               |
| TOTAL IMPURITIES                                                           | Maximum 2.0%                                                                                                                                                                                                     | 0.1%²                                                                            |   |   | ND (<0.05%)²                                                 | ND (<0.05%)                               |
| AEROBIC MICROBIAL COUNT (TAMC)                                             | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                       |   |   | < 10 cfu/g                                                   | < 10 cfu/g                                |
| MOLDS AND YEASTS COUNT (TYMC)                                              | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                       |   |   | < 10 cfu/g                                                   | < 10 cfu/g                                |
| Escherichia coli                                                           | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                       |   |   | Absent /1g                                                   | Absent /1g                                |
| Staphylococcus aureus                                                      | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                       |   |   | Absent /1g                                                   | Absent /1g                                |
| Pseudomonas aeruginosa                                                     | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                       |   |   | Absent /1g                                                   | Absent /1g                                |
| Salmonella spp                                                             | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                      |   |   | Absent /10g                                                  | Absent /10g                               |
| SAMPLING DATE (YY/MM/DD)                                                   |                                                                                                                                                                                                                  | Not Applied                                                                      |   |   | 14-07-09                                                     | 14-10-09                                  |
| ACTUAL TEST DATE (YY/MM/DD)                                                |                                                                                                                                                                                                                  | 14-04-11                                                                         |   |   | 14-07-10                                                     | 14-10-11                                  |
| METHOD REVISION NUMBER                                                     |                                                                                                                                                                                                                  | USGP-0221-Version 00                                                             |   |   | USGP-0221-Version 00                                         | USGP-0221-Version 00                      |
| Footnotes: ND (Not Detectable)<br>1. OOT-14-11-042.<br>2. OOT-14-08-002.   |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                              |                                           |

PREPARED BY: PLS L. Barragán 15-01-29  
STABILITY COORDINATOR

REVIEWED BY: S. Arayo | R. Cordero  
15-01-29 | 15-01-29  
ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: [Signature] 15-01-29  
QUALITY ASSURANCE

STABILITY REPORT

|                                                                            |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                                |                                           |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---|---|----------------------------------------------------------------|-------------------------------------------|
| STABILITY REPORT NUMBER: To be defined                                     |                                                                                                                                                                                                                  | USGP PROCAPS - SOFGEN                                                            |   |   |                                                                |                                           |
| CONDITION: Holding Time (14°C To 28°C and 70%of Relative Humidity Maximum) |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                                |                                           |
| PERFORMED BY: L. Barragán                                                  |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                                |                                           |
| PROTOCOL NUMBER: PD480                                                     |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                                |                                           |
| MANUFACTURING DATE: 14-03-19                                               |                                                                                                                                                                                                                  | PRODUCT NAME: Vitamin D3 800 IU SGCs                                             |   |   |                                                                |                                           |
| PACKAGING DATE: 14-03-28                                                   |                                                                                                                                                                                                                  | CODE / LOT NUMBER: 400004764 / 1026333                                           |   |   |                                                                |                                           |
| DATE STUDY STARTED: 14-04-09                                               |                                                                                                                                                                                                                  | API RECEIVING NUMBER: 1020053                                                    |   |   |                                                                |                                           |
| PACKAGING: Polyethylene dark bags x 100 capsules                           |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                                |                                           |
|                                                                            |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                                |                                           |
|                                                                            |                                                                                                                                                                                                                  | TIME MONTHS                                                                      |   |   |                                                                |                                           |
| TESTS                                                                      | ACCEPTANCE CRITERIA                                                                                                                                                                                              | 0                                                                                | 1 | 2 | 3                                                              | 6                                         |
| CAPSULE DESCRIPTION                                                        | Pink, soft-gelatin, oval-shape capsule. It contains a slightly yellow oily liquid, which is free from foreign matter. Capsules have good sheen, seal and hardness. Each capsule has a logo printed in white ink. | Meets                                                                            |   |   | Meets                                                          | Meets                                     |
| PACKAGING DESCRIPTION                                                      | Polyethylene dark bag x 100 capsules.                                                                                                                                                                            | Meets                                                                            |   |   | Meets                                                          | Meets                                     |
| UNIFORMITY OF DOSAGE (Content Uniformity)                                  | The Acceptance Value obtained is less than or equal to 15.0 (L1).                                                                                                                                                | AV= 2.9<br>97.5%, 99.6%, 96.8%, 98.2%, 99.2%, 97.2%, 98.7%, 100.6%, 98.0%, 99.2% |   |   |                                                                |                                           |
| DISINTEGRATION <sup>1</sup>                                                | Maximum 30 minutes                                                                                                                                                                                               | 12, 11, 11, 12, 10, 11 minutes (dissolution time of the shell)                   |   |   | 12, 11, 11, 10, 11, 12 minutes (dissolution time of the shell) | 7, 7, 6, 6, 6, 7 minutes (disintegration) |
| VALUE PEROXIDE                                                             | Maximum 20 ppm                                                                                                                                                                                                   | < 20 ppm                                                                         |   |   | < 20 ppm                                                       | < 20 ppm                                  |
| ASSAY                                                                      | Vitamin E: Not less than 0.1%                                                                                                                                                                                    | 0.3%                                                                             |   |   | 0.2%                                                           | 0.2%                                      |
| ASSAY                                                                      | Vitamin D3 800 UI/cap; 90.0 – 115.0% (720 – 920 UI/cap.)                                                                                                                                                         | 101.0%                                                                           |   |   | 101.5%                                                         | 103.4%                                    |
| TRANSCHOLECALCIFEROL                                                       | Maximum 1.5%                                                                                                                                                                                                     | ND (<0.05%)                                                                      |   |   | ND (<0.05%)                                                    | ND (<0.05%)                               |
| ANY OTHER INDIVIDUAL IMPURITY                                              | Maximum 0.5%                                                                                                                                                                                                     | RRT 1.17= 0.1%                                                                   |   |   | ND (<0.05%)                                                    | ND (<0.05%)                               |
| TOTAL IMPURITIES                                                           | Maximum 2.0%                                                                                                                                                                                                     | 0.1% <sup>2</sup>                                                                |   |   | ND (<0.05%) <sup>2</sup>                                       | ND (<0.05%)                               |
| AEROBIC MICROBIAL COUNT (TAMC)                                             | 100 cfu/g maximum.                                                                                                                                                                                               | < 10 cfu/g                                                                       |   |   | < 10 cfu/g                                                     | < 10 cfu/g                                |
| MOLDS AND YEASTS COUNT (TYMC)                                              | 10 cfu/g maximum.                                                                                                                                                                                                | < 10 cfu/g                                                                       |   |   | < 10 cfu/g                                                     | < 10 cfu/g                                |
| Escherichia coli                                                           | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                       |   |   | Absent /1g                                                     | Absent /1g                                |
| Staphylococcus aureus                                                      | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                       |   |   | Absent /1g                                                     | Absent /1g                                |
| Pseudomonas aeruginosa                                                     | Absent /1g                                                                                                                                                                                                       | Absent /1g                                                                       |   |   | Absent /1g                                                     | Absent /1g                                |
| Salmonella spp                                                             | Absent /10g                                                                                                                                                                                                      | Absent /10g                                                                      |   |   | Absent /10g                                                    | Absent /10g                               |
| SAMPLING DATE (YY/MM/DD)                                                   |                                                                                                                                                                                                                  | Not Applied                                                                      |   |   | 14-07-09                                                       | 14-10-09                                  |
| ACTUAL TEST DATE (YY/MM/DD)                                                |                                                                                                                                                                                                                  | 14-04-11                                                                         |   |   | 14-07-10                                                       | 14-10-11                                  |
| METHOD REVISION NUMBER                                                     |                                                                                                                                                                                                                  | USGP-0221-Version 00                                                             |   |   | USGP-0221-Version 00                                           | USGP-0221-Version 00                      |
| Footnotes: ND (Not Detectable)<br>1. OOT-14-11-042.<br>2. OOT-14-08-002.   |                                                                                                                                                                                                                  |                                                                                  |   |   |                                                                |                                           |

PREPARED BY: PILS L. Barragán

15-01-29

STABILITY COORDINATOR

S. Araya

13-01-29

15-01-29

ANALYTICAL DEVELOPMENT / REGULATORY AFFAIRS

APPROVED BY: J. Aguirre

15-01-29

QUALITY ASSURANCE