

## Stability Study Summary

### Anastrozole 1 mg film-coated tablets

|                                    |                                                       |
|------------------------------------|-------------------------------------------------------|
| Version number:                    | SSS.NUS.ANA.tab1.001 (7.0)                            |
| Supersedes document of issue date: | SSS.NUS.ANA.tab1.001 (6.0), electronically controlled |
| Number of appendices:              | None                                                  |
| Prepared by:                       | M. Jusic                                              |
| Document length:                   | 25 pages                                              |

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1 Introduction

This Stability Study Summary presents the stability data regarding Anastrozole 1 mg film-coated tablets as described in the Stability Data Evaluation (SDE.NUS.ANA.tab1.001).

Explanation of terms used in this stability study summary:

Long term study: 25°C / 60% RH

Alternative long term study: 30°C / 65% RH

Accelerated study: 40°C / 75% RH

C: Complies with specification

NC: Does not comply with specification

---: Not performed or no results available

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2 Overview long term stability data 25°C / 60% RH

2.1 PVC/PE/PVDC/Aluminium blister

In this part of the Stability Study Summary the stability data of the Anastrozole 1 mg film-coated tablets stored in PVC/PE/PVDC/Al blister at 25°C / 60% RH are presented.

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|----------------------------------------|------------------|-----|--------|-----|--------|----------------------|--------|-------------------|--------|-----|--------|-----|--------|-----|--------|-----|--------|-----|-----|-----|
| Product / strength:                    | Anastrozole 1 mg |     |        |     |        | Packaged lot number: |        | 05G11IS F         |        |     |        |     |        |     |        |     |        |     |     |     |
| Storage condition:                     | 25 °C/60 % RH    |     |        |     |        | Batch size:          |        | 1,000,000 tablets |        |     |        |     |        |     |        |     |        |     |     |     |
| Study start date:                      | 05-08-05         |     |        |     |        | Packaging site:      |        | Synthon Hispania  |        |     |        |     |        |     |        |     |        |     |     |     |
| Tests ↓      Time in months →          | 0                |     | 3      |     | 6      |                      | 9      |                   | 12     |     | 18     |     | 24     |     | 36     |     | 48     |     | 60  |     |
| Appearance:                            | C                |     | C      |     | C      |                      | C      |                   | C      |     | C      |     | C      |     | C      |     | C      |     | C   |     |
| Water content (%):                     | 5.3              |     | 5.4    |     | 5.1    |                      | 5.5    |                   | 5.7    |     | 5.3    |     | 5.4    |     | 5.6    |     | 5.5    |     |     |     |
| Dissolution (%):                       | min              | avg | min    | avg | min    | avg                  | min    | avg               | min    | avg | min    | avg | min    | avg | min    | avg | min    | avg | min | avg |
| - in 15 minutes                        | 97               | 99  | 96     | 99  | 98     | 99                   | 95     | 97                | 96     | 98  | 98     | 99  | 96     | 97  | 96     | 98  | 100    | 102 |     |     |
| Identification (ANA)                   |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC retention time                  | C                |     | C      |     | C      |                      | C      |                   | C      |     | C      |     | C      |     | C      |     | C      |     |     |     |
| Assay (ANA)                            |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC (mg/tab)                        | 0.99             |     | 0.97   |     | 0.98   |                      | 0.99   |                   | 0.99   |     | 0.98   |     | 0.98   |     | 0.98   |     | 1.00   |     |     |     |
| - % of declared value                  | 98.7             |     | 96.9   |     | 97.7   |                      | 99.0   |                   | 98.7   |     | 97.5   |     | 97.8   |     | 98.0   |     | 99.6   |     |     |     |
| - % of initial value                   | 100.0            |     | 98.2   |     | 99.0   |                      | 100.3  |                   | 100.0  |     | 98.8   |     | 99.1   |     | 99.3   |     | 100.9  |     |     |     |
| Impurities (HPLC):                     |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
| - Triazonitrile (E#401) (%)            | 0.06             |     | 0.06   |     | ≤ 0.05 |                      | 0.06   |                   | 0.06   |     | 0.06   |     | ≤ 0.05 |     | 0.06   |     | 0.06   |     |     |     |
| - Anastrocol (E/406) (%)               | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |                      | ≤ 0.05 |                   | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Anastrochloride (E/407) (%)          | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |                      | ≤ 0.05 |                   | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Largest unspecified impurity (%)     | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |                      | 0.06   |                   | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total unspecified impurities (%)     | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |                      | 0.06   |                   | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total impurities (%)                 | 0.06             |     | 0.06   |     | ≤ 0.05 |                      | 0.11   |                   | 0.06   |     | 0.06   |     | ≤ 0.05 |     | 0.06   |     | 0.06   |     |     |     |
| Microbial contamination:               |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
| - Total aerobic microbial count (TAMC) | C                |     | ---    |     | C      |                      | ---    |                   | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Total combined yeasts/moulds count   | C                |     | ---    |     | C      |                      | ---    |                   | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Escherichia coli                     | C                |     | ---    |     | C      |                      | ---    |                   | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |

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|----------------------------------------|------------------|------------------|-----|--------|-----|--------|-----|----------------------------------|-----|--------|-----|--------|-----|--------|-----|--------|-----|--------|-----|-----|-----|
| Product / strength:                    |                  | Anastrozole 1 mg |     |        |     |        |     | Packaged lot number: 05G14IS F   |     |        |     |        |     |        |     |        |     |        |     |     |     |
| Storage condition:                     |                  | 25°C/60 % RH     |     |        |     |        |     | Batch size: 1.000.000 tablets    |     |        |     |        |     |        |     |        |     |        |     |     |     |
| Study start date:                      |                  | 05-08-05         |     |        |     |        |     | Packaging site: Synthon Hispania |     |        |     |        |     |        |     |        |     |        |     |     |     |
| Tests ↓                                | Time in months → | 0                |     | 3      |     | 6      |     | 9                                |     | 12     |     | 18     |     | 24     |     | 36     |     | 48     |     | 60  |     |
| Appearance:                            |                  | C                |     | C      |     | C      |     | C                                |     | C      |     | C      |     | C      |     | C      |     | C      |     | C   |     |
| Water content (%):                     |                  | 5.3              |     | 5.4    |     | 5.1    |     | 5.5                              |     | 5.7    |     | 5.6    |     | 5.4    |     | 5.7    |     | 5.5    |     |     |     |
| Dissolution (%):                       |                  | min              | avg | min    | avg | min    | avg | min                              | avg | min    | avg | min    | avg | min    | avg | min    | avg | min    | avg | min | avg |
| - in 15 minutes                        |                  | 94               | 96  | 95     | 98  | 96     | 97  | 93                               | 97  | 96     | 97  | 95     | 96  | 97     | 99  | 91     | 95  | 99     | 101 |     |     |
| Identification (ANA)                   |                  |                  |     |        |     |        |     |                                  |     |        |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC retention time                  |                  | C                |     | C      |     | C      |     | C                                |     | C      |     | C      |     | C      |     | C      |     | C      |     |     |     |
| Assay (ANA)                            |                  |                  |     |        |     |        |     |                                  |     |        |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC (mg/tab)                        |                  | 0.98             |     | 0.97   |     | 0.97   |     | 0.97                             |     | 1.04   |     | 0.97   |     | 0.97   |     | 0.95   |     | 0.99   |     |     |     |
| - % of declared value                  |                  | 98.3             |     | 96.8   |     | 97.0   |     | 97.3                             |     | 104.2  |     | 96.7   |     | 97.2   |     | 95.0   |     | 98.6   |     |     |     |
| - % of initial value                   |                  | 100.0            |     | 98.5   |     | 98.7   |     | 99.0                             |     | 106.0  |     | 98.4   |     | 98.9   |     | 96.6   |     | 100.3  |     |     |     |
| Impurities (HPLC):                     |                  |                  |     |        |     |        |     |                                  |     |        |     |        |     |        |     |        |     |        |     |     |     |
| - Triazolnitrile (E#401) (%)           |                  | 0.07             |     | 0.06   |     | 0.06   |     | 0.06                             |     | 0.06   |     | 0.06   |     | ≤ 0.05 |     | 0.06   |     | 0.06   |     |     |     |
| - Anastrocol (E/406) (%)               |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05                           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Anastrochloride (E/407) (%)          |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05                           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Largest unspecified impurity (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05                           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total unspecified impurities (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05                           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total impurities (%)                 |                  | 0.07             |     | 0.06   |     | 0.06   |     | 0.06                             |     | 0.06   |     | 0.06   |     | ≤ 0.05 |     | 0.06   |     | 0.06   |     |     |     |
| Microbial contamination:               |                  |                  |     |        |     |        |     |                                  |     |        |     |        |     |        |     |        |     |        |     |     |     |
| - Total aerobic microbial count (TAMC) |                  | C                |     | ---    |     | C      |     | ---                              |     | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Total combined yeasts/moulds count   |                  | C                |     | ---    |     | C      |     | ---                              |     | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Escherichia coli                     |                  | C                |     | ---    |     | C      |     | ---                              |     | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |

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|----------------------------------------|------------------|-----|--------|-----|--------|-----|----------------------|-----|-------------------|-----|--------|-----|--------|-----|--------|-----|--------|-----|-----|-----|
| Product / strength:                    | Anastrozole 1 mg |     |        |     |        |     | Packaged lot number: |     | 05G19IS F         |     |        |     |        |     |        |     |        |     |     |     |
| Storage condition:                     | 25 °C/60 % RH    |     |        |     |        |     | Batch size:          |     | 1,000,000 tablets |     |        |     |        |     |        |     |        |     |     |     |
| Study start date:                      | 05-08-05         |     |        |     |        |     | Packaging site:      |     | Synthon Hispania  |     |        |     |        |     |        |     |        |     |     |     |
| Tests ↓      Time in months →          | 0                |     | 3      |     | 6      |     | 9                    |     | 12                |     | 18     |     | 24     |     | 36     |     | 48     |     | 60  |     |
| Appearance:                            | C                |     | C      |     | C      |     | C                    |     | C                 |     | C      |     | C      |     | C      |     | C      |     | C   |     |
| Water content (%):                     | 5.3              |     | 5.2    |     | 5.1    |     | 5.5                  |     | 5.6               |     | 5.3    |     | 5.4    |     | 5.7    |     | 5.5    |     | 5.5 |     |
| Dissolution (%):                       | min              | avg | min    | avg | min    | avg | min                  | avg | min               | avg | min    | avg | min    | avg | min    | avg | min    | avg | min | avg |
| - in 15 minutes                        | 92               | 96  | 95     | 98  | 97     | 99  | 90                   | 95  | 96                | 99  | 95     | 96  | 94     | 96  | 91     | 95  | 96     | 99  |     |     |
| Identification (ANA)                   |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC retention time                  | C                |     | C      |     | C      |     | C                    |     | C                 |     | C      |     | C      |     | C      |     | C      |     | C   |     |
| Assay (ANA)                            |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC (mg/tab)                        | 0.99             |     | 0.97   |     | 0.99   |     | 0.98                 |     | 1.02              |     | 0.98   |     | 1.00   |     | 0.97   |     | 0.99   |     |     |     |
| - % of declared value                  | 99.1             |     | 96.8   |     | 98.6   |     | 98.4                 |     | 102.3             |     | 97.8   |     | 99.5   |     | 97.0   |     | 98.6   |     |     |     |
| - % of initial value                   | 100.0            |     | 97.7   |     | 99.5   |     | 99.3                 |     | 103.2             |     | 98.7   |     | 100.4  |     | 97.9   |     | 99.5   |     |     |     |
| Impurities (HPLC):                     |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - Triazolonitrile (E#401) (%)          | 0.06             |     | 0.06   |     | 0.06   |     | 0.06                 |     | 0.06              |     | 0.06   |     | 0.06   |     | 0.07   |     | 0.06   |     |     |     |
| - Anastrocol (E/406) (%)               | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Anastrochloride (E/407) (%)          | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Largest unspecified impurity (%)     | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total unspecified impurities (%)     | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total impurities (%)                 | 0.06             |     | 0.06   |     | 0.06   |     | 0.06                 |     | 0.06              |     | 0.06   |     | 0.06   |     | 0.07   |     | 0.07   |     |     |     |
| Microbial contamination:               |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - Total aerobic microbial count (TAMC) | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     | C   |     |
| - Total combined yeasts/moulds count   | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     | C   |     |
| - Escherichia coli                     | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     | C   |     |

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2.2 HDPE Bulk container 20 L

In this part of the Stability Study Summary the stability data of the Anastrozole 1 mg film-coated tablets stored in HDPE Bulk container 20 L at 25°C / 60% RH are presented.

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|----------------------------------------|------------------|------------------|----------|---------|---------|----------------------|-----------------|------------------|--|--|-----|-----|-----|
| Product / strength:                    |                  | Anastrozole 1 mg |          |         |         | Packaged lot number: |                 | 05G11S G         |  |  |     |     |     |
| Storage condition:                     |                  | 25 °C/60 % RH    |          |         |         | Batch size:          |                 | 1,000,000        |  |  |     |     |     |
| Study start date:                      |                  | 05-08-05         |          |         |         | Packaging site:      |                 | Synthon Hispania |  |  |     |     |     |
| Tests ↓                                | Time in months → | 0                | 6        | 12      | 24      | 36                   | STUDY COMPLETED |                  |  |  |     |     |     |
| Appearance:                            |                  | C                | C        | C       | C       |                      |                 |                  |  |  |     |     |     |
| Water content (%):                     |                  | 5.3              | 4.9      | 4.8     | 5.0     |                      |                 |                  |  |  |     |     |     |
| Dissolution (%):                       |                  | min              | avg      | min     | avg     | min                  |                 |                  |  |  | avg | min | avg |
| - in 15 minutes                        |                  | 97   99          | 98   100 | 95   98 | 96   99 |                      |                 |                  |  |  |     |     |     |
| Identification (ANA)                   |                  |                  |          |         |         |                      |                 |                  |  |  |     |     |     |
| - HPLC retention time                  |                  | C                | C        | C       | C       |                      |                 |                  |  |  |     |     |     |
| Assay (ANA)                            |                  |                  |          |         |         |                      |                 |                  |  |  |     |     |     |
| - HPLC (mg/tab)                        |                  | 0.99             | 1.00     | 1.01    | 0.99    |                      |                 |                  |  |  |     |     |     |
| - % of declared value                  |                  | 98.7             | 99.8     | 100.5   | 98.8    |                      |                 |                  |  |  |     |     |     |
| - % of initial value                   |                  | 100.0            | 101.1    | 101.8   | 100.1   |                      |                 |                  |  |  |     |     |     |
| Impurities (HPLC):                     |                  |                  |          |         |         |                      |                 |                  |  |  |     |     |     |
| - Triazonitrile (E#401) (%)            |                  | 0.06             | ≤ 0.05   | 0.06    | 0.05    |                      |                 |                  |  |  |     |     |     |
| - Anastrocol (E/406) (%)               |                  | ≤ 0.05           | ≤ 0.05   | ≤ 0.05  | ≤ 0.05  |                      |                 |                  |  |  |     |     |     |
| - Anastrochloride (E/407) (%)          |                  | ≤ 0.05           | ≤ 0.05   | ≤ 0.05  | ≤ 0.05  |                      |                 |                  |  |  |     |     |     |
| - Largest unspecified impurity (%)     |                  | ≤ 0.05           | ≤ 0.05   | ≤ 0.05  | ≤ 0.05  |                      |                 |                  |  |  |     |     |     |
| - Total unspecified impurities (%)     |                  | ≤ 0.05           | ≤ 0.05   | ≤ 0.05  | ≤ 0.05  |                      |                 |                  |  |  |     |     |     |
| - Total impurities (%)                 |                  | 0.06             | ≤ 0.05   | 0.06    | 0.05    |                      |                 |                  |  |  |     |     |     |
| Microbial contamination:               |                  |                  |          |         |         |                      |                 |                  |  |  |     |     |     |
| - Total aerobic microbial count (TAMC) |                  | C                | C        | C       | C       |                      |                 |                  |  |  |     |     |     |
| - Total combined yeasts/moulds count   |                  | C                | C        | C       | C       |                      |                 |                  |  |  |     |     |     |
| - Escherichia coli                     |                  | C                | C        | C       | C       |                      |                 |                  |  |  |     |     |     |

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|----------------------------------------|------------------|------------------|-----|--------|-----|----------------------|-----|-------------------|-----|-----------------|--|
| Product / strength:                    |                  | Anastrozole 1 mg |     |        |     | Packaged lot number: |     | 05G14IS G         |     |                 |  |
| Storage condition:                     |                  | 25 °C/60 % RH    |     |        |     | Batch size:          |     | 1.000.000 tablets |     |                 |  |
| Study start date:                      |                  | 05-08-05         |     |        |     | Packaging site:      |     | Synthon Hispania  |     |                 |  |
| Tests ↓                                | Time in months → | 0                |     | 6      |     | 12                   |     | 24                |     | 36              |  |
| Appearance:                            |                  | C                |     | C      |     | C                    |     | C                 |     | STUDY COMPLETED |  |
| Water content (%):                     |                  | 5.3              |     | 5.0    |     | 4.9                  |     | 4.7               |     |                 |  |
| Dissolution (%):                       |                  | min              | avg | min    | avg | min                  | avg | min               | avg |                 |  |
| - in 15 minutes                        |                  | 94               | 96  | 99     | 100 | 95                   | 97  | 97                | 98  |                 |  |
| Identification (ANA)                   |                  |                  |     |        |     |                      |     |                   |     |                 |  |
| - HPLC retention time                  |                  | C                |     | C      |     | C                    |     | C                 |     |                 |  |
| Assay (ANA)                            |                  |                  |     |        |     |                      |     |                   |     |                 |  |
| - HPLC (mg/tab)                        |                  | 0.98             |     | 0.99   |     | 0.99                 |     | 0.96              |     |                 |  |
| - % of declared value                  |                  | 98.3             |     | 98.9   |     | 99.3                 |     | 96.0              |     |                 |  |
| - % of initial value                   |                  | 100.0            |     | 100.6  |     | 101.0                |     | 97.7              |     |                 |  |
| Impurities (HPLC):                     |                  |                  |     |        |     |                      |     |                   |     |                 |  |
| - Triazonitrile (E#401) (%)            |                  | 0.07             |     | 0.06   |     | 0.06                 |     | 0.05              |     |                 |  |
| - Anastrocol (E/406) (%)               |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     |                 |  |
| - Anastrochloride (E/407) (%)          |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     |                 |  |
| - Largest unspecified impurity (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     |                 |  |
| - Total unspecified impurities (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     |                 |  |
| - Total impurities (%)                 |                  | 0.07             |     | 0.06   |     | 0.06                 |     | 0.05              |     |                 |  |
| Microbial contamination:               |                  |                  |     |        |     |                      |     |                   |     |                 |  |
| - Total aerobic microbial count (TAMC) |                  | C                |     | C      |     | C                    |     | C                 |     |                 |  |
| - Total combined yeasts/moulds count   |                  | C                |     | C      |     | C                    |     | C                 |     |                 |  |
| - Escherichia coli                     |                  | C                |     | C      |     | C                    |     | C                 |     |                 |  |

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| Product / strength:                    |                  | Anastrozole 1 mg |     |        |     | Packaged lot number: |     | 05G19IS G         |     |    |                 |
|----------------------------------------|------------------|------------------|-----|--------|-----|----------------------|-----|-------------------|-----|----|-----------------|
| Storage condition:                     |                  | 25 °C/60 % RH    |     |        |     | Batch size:          |     | 1,000,000 tablets |     |    |                 |
| Study start date:                      |                  | 05-08-05         |     |        |     | Packaging site:      |     | Synthon Hispania  |     |    |                 |
| Tests ↓                                | Time in months → | 0                |     | 6      |     | 12                   |     | 24                |     | 36 | STUDY COMPLETED |
| Appearance:                            |                  | C                |     | C      |     | C                    |     | C                 |     |    |                 |
| Water content (%):                     |                  | 5.3              |     | 4.9    |     | 4.7                  |     | 4.9               |     |    |                 |
| Dissolution (%):                       |                  | min              | avg | min    | avg | min                  | avg | min               | avg |    |                 |
| - in 15 minutes                        |                  | 92               | 96  | 95     | 97  | 93                   | 96  | 96                | 98  |    |                 |
| Identification (ANA)                   |                  |                  |     |        |     |                      |     |                   |     |    |                 |
| - HPLC retention time                  |                  | C                |     | C      |     | C                    |     | C                 |     |    |                 |
| Assay (ANA)                            |                  |                  |     |        |     |                      |     |                   |     |    |                 |
| - HPLC (mg/tab)                        |                  | 0.99             |     | 1.00   |     | 0.99                 |     | 0.97              |     |    |                 |
| - % of declared value                  |                  | 99.1             |     | 99.5   |     | 99.2                 |     | 96.5              |     |    |                 |
| - % of initial value                   |                  | 100.0            |     | 100.4  |     | 100.1                |     | 97.4              |     |    |                 |
| Impurities (HPLC):                     |                  |                  |     |        |     |                      |     |                   |     |    |                 |
| - Triazolnitrile (E#401) (%)           |                  | 0.06             |     | 0.06   |     | 0.06                 |     | 0.06              |     |    |                 |
| - Anastrocol (E/406) (%)               |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     |    |                 |
| - Anastrochloride (E/407) (%)          |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     |    |                 |
| - Largest unspecified impurity (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     |    |                 |
| - Total unspecified impurities (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     |    |                 |
| - Total impurities (%)                 |                  | 0.06             |     | 0.06   |     | 0.06                 |     | 0.06              |     |    |                 |
| Microbial contamination:               |                  |                  |     |        |     |                      |     |                   |     |    |                 |
| - Total aerobic microbial count (TAMC) |                  | C                |     | C      |     | C                    |     | C                 |     |    |                 |
| - Total combined yeasts/moulds count   |                  | C                |     | C      |     | C                    |     | C                 |     |    |                 |
| - Escherichia coli                     |                  | C                |     | C      |     | C                    |     | C                 |     |    |                 |

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3 Overview alternative long term stability data 30 °C / 65 % RH

3.1 PVC/PE/PVDC/Aluminium blister

In this part of the Stability Study Summary the stability data of the Anastrozole 1 mg film-coated tablets stored in PVC/PE/PVDC/Al blister at 30°C / 65% RH are presented.

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|                                        |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
|----------------------------------------|------------------|-----|--------|-----|--------|----------------------|--------|-------------------|--------|-----|--------|-----|--------|-----|--------|-----|--------|-----|-----|-----|
| Product / strength:                    | Anastrozole 1 mg |     |        |     |        | Packaged lot number: |        | 05G11S F          |        |     |        |     |        |     |        |     |        |     |     |     |
| Storage condition:                     | 30 °C/65 % RH    |     |        |     |        | Batch size:          |        | 1,000,000 tablets |        |     |        |     |        |     |        |     |        |     |     |     |
| Study start date:                      | 05-08-05         |     |        |     |        | Packaging site:      |        | Synthon Hispania  |        |     |        |     |        |     |        |     |        |     |     |     |
| Tests ↓      Time in months →          | 0                |     | 3      |     | 6      |                      | 9      |                   | 12     |     | 18     |     | 24     |     | 36     |     | 48     |     | 60  |     |
| Appearance:                            | C                |     | C      |     | C      |                      | C      |                   | C      |     | C      |     | C      |     | C      |     | C      |     |     |     |
| Water content (%):                     | 5.3              |     | 5.5    |     | 5.3    |                      | 5.7    |                   | 5.8    |     | 5.5    |     | 5.5    |     | 5.8    |     | 5.5    |     |     |     |
| Dissolution (%):                       | min              | avg | min    | avg | min    | avg                  | min    | avg               | min    | avg | min    | avg | min    | avg | min    | avg | min    | avg | min | avg |
| - in 15 minutes                        | 97               | 99  | 98     | 100 | 97     | 99                   | 93     | 95                | 94     | 96  | 94     | 96  | 98     | 99  | 96     | 98  | 101    | 103 |     |     |
| Identification (ANA)                   |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC retention time                  | C                |     | C      |     | C      |                      | C      |                   | C      |     | C      |     | C      |     | C      |     | C      |     |     |     |
| Assay (ANA)                            |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC (mg/tab)                        | 0.99             |     | 0.97   |     | 1.00   |                      | 0.99   |                   | 1.00   |     | 0.98   |     | 0.97   |     | 0.98   |     | 0.99   |     |     |     |
| - % of declared value                  | 98.7             |     | 97.0   |     | 100.0  |                      | 98.7   |                   | 99.8   |     | 97.5   |     | 97.3   |     | 97.6   |     | 98.7   |     |     |     |
| - % of initial value                   | 100.0            |     | 98.3   |     | 101.3  |                      | 100.0  |                   | 101.1  |     | 98.8   |     | 98.6   |     | 98.9   |     | 100.0  |     |     |     |
| Impurities (HPLC):                     |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
| - Triazonitrile (E#401) (%)            | 0.06             |     | 0.06   |     | 0.06   |                      | 0.06   |                   | 0.06   |     | 0.06   |     | ≤ 0.05 |     | 0.06   |     | 0.06   |     |     |     |
| - Anastrocol (E/406) (%)               | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |                      | ≤ 0.05 |                   | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Anastrochloride (E/407) (%)          | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |                      | ≤ 0.05 |                   | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Largest unspecified impurity (%)     | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |                      | 0.06   |                   | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total unspecified impurities (%)     | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |                      | 0.06   |                   | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total impurities (%)                 | 0.06             |     | 0.06   |     | 0.06   |                      | 0.11   |                   | 0.06   |     | 0.06   |     | ≤ 0.05 |     | 0.06   |     | 0.06   |     |     |     |
| Microbial contamination:               |                  |     |        |     |        |                      |        |                   |        |     |        |     |        |     |        |     |        |     |     |     |
| - Total aerobic microbial count (TAMC) | C                |     | ---    |     | C      |                      | ---    |                   | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Total combined yeasts/moulds count   | C                |     | ---    |     | C      |                      | ---    |                   | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Escherichia coli                     | C                |     | ---    |     | C      |                      | ---    |                   | C      |     | ---    |     | C      |     | C      |     | C      |     |     |     |

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|                                        |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
|----------------------------------------|------------------|-----|--------|-----|--------|-----|----------------------|-----|-------------------|-----|--------|-----|--------|-----|--------|-----|--------|-----|-----|-----|
| Product / strength:                    | Anastrozole 1 mg |     |        |     |        |     | Packaged lot number: |     | 05G14IS F         |     |        |     |        |     |        |     |        |     |     |     |
| Storage condition:                     | 30 °C/65 % RH    |     |        |     |        |     | Batch size:          |     | 1.000.000 tablets |     |        |     |        |     |        |     |        |     |     |     |
| Study start date:                      | 05-08-05         |     |        |     |        |     | Packaging site:      |     | Synthon Hispania  |     |        |     |        |     |        |     |        |     |     |     |
| Tests ↓      Time in months →          | 0                |     | 3      |     | 6      |     | 9                    |     | 12                |     | 18     |     | 24     |     | 36     |     | 48     |     | 60  |     |
| Appearance:                            | C                |     | C      |     | C      |     | C                    |     | C                 |     | C      |     | C      |     | C      |     | C      |     | C   |     |
| Water content (%):                     | 5.3              |     | 5.5    |     | 5.1    |     | 5.6                  |     | 5.8               |     | 5.5    |     | 5.4    |     | 5.8    |     | 5.5    |     |     |     |
| Dissolution (%):                       | min              | avg | min    | avg | min    | avg | min                  | avg | min               | avg | min    | avg | min    | avg | min    | avg | min    | avg | min | avg |
| - in 15 minutes                        | 94               | 96  | 96     | 97  | 93     | 95  | 90                   | 94  | 92                | 94  | 89     | 93  | 95     | 96  | 93     | 97  | 98     | 99  |     |     |
| Identification (ANA)                   |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC retention time                  | C                |     | C      |     | C      |     | C                    |     | C                 |     | C      |     | C      |     | C      |     | C      |     |     |     |
| Assay (ANA)                            |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC (mg/tab)                        | 0.98             |     | 0.96   |     | 0.99   |     | 0.98                 |     | 1.04              |     | 0.97   |     | 0.97   |     | 0.97   |     | 0.99   |     |     |     |
| - % of declared value                  | 98.3             |     | 95.9   |     | 98.7   |     | 97.8                 |     | 103.8             |     | 96.6   |     | 97.4   |     | 97.0   |     | 99.3   |     |     |     |
| - % of initial value                   | 100.0            |     | 97.6   |     | 100.4  |     | 99.5                 |     | 105.6             |     | 98.3   |     | 99.1   |     | 98.7   |     | 101.0  |     |     |     |
| Impurities (HPLC):                     |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - Triazonitrile (E#401) (%)            | 0.07             |     | 0.06   |     | ≤ 0.05 |     | 0.06                 |     | 0.06              |     | 0.06   |     | ≤ 0.05 |     | 0.06   |     | ≤ 0.05 |     |     |     |
| - Anastrocol (E/406) (%)               | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Anastrochloride (E/407) (%)          | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Largest unspecified impurity (%)     | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total unspecified impurities (%)     | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total impurities (%)                 | 0.07             |     | 0.06   |     | ≤ 0.05 |     | 0.06                 |     | 0.06              |     | 0.06   |     | ≤ 0.05 |     | 0.06   |     | ≤ 0.05 |     |     |     |
| Microbial contamination:               |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - Total aerobic microbial count (TAMC) | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Total combined yeasts/moulds count   | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Escherichia coli                     | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     |     |     |

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|----------------------------------------|------------------|------------------|-----|--------|-----|--------|-----|----------------------|-----|-------------------|-----|--------|-----|--------|-----|--------|-----|--------|-----|-----|-----|
| Product / strength:                    |                  | Anastrozole 1 mg |     |        |     |        |     | Packaged lot number: |     | 05G19IS F         |     |        |     |        |     |        |     |        |     |     |     |
| Storage condition:                     |                  | 30 °C/65 % RH    |     |        |     |        |     | Batch size:          |     | 1,000,000 tablets |     |        |     |        |     |        |     |        |     |     |     |
| Study start date:                      |                  | 05-08-05         |     |        |     |        |     | Packaging site:      |     | Synthon Hispania  |     |        |     |        |     |        |     |        |     |     |     |
| Tests ↓                                | Time in months → | 0                |     | 3      |     | 6      |     | 9                    |     | 12                |     | 18     |     | 24     |     | 36     |     | 48     |     | 60  |     |
| Appearance:                            |                  | C                |     | C      |     | C      |     | C                    |     | C                 |     | C      |     | C      |     | C      |     | C      |     |     |     |
| Water content (%):                     |                  | 5.3              |     | 5.4    |     | 5.3    |     | 5.7                  |     | 5.9               |     | 5.5    |     | 5.3    |     | 5.9    |     | 5.6    |     |     |     |
| Dissolution (%):                       |                  | min              | avg | min    | avg | min    | avg | min                  | avg | min               | avg | min    | avg | min    | avg | min    | avg | min    | avg | min | avg |
| - in 15 minutes                        |                  | 92               | 96  | 96     | 99  | 93     | 96  | 88                   | 93  | 85                | 91  | 89     | 91  | 89     | 93  | 92     | 93  | 98     | 100 |     |     |
| Identification (ANA)                   |                  |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC retention time                  |                  | C                |     | C      |     | C      |     | C                    |     | C                 |     | C      |     | C      |     | C      |     | C      |     |     |     |
| Assay (ANA)                            |                  |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - HPLC (mg/tab)                        |                  | 0.99             |     | 0.97   |     | 0.99   |     | 0.97                 |     | 1.01              |     | 0.97   |     | 0.99   |     | 0.98   |     | 0.99   |     |     |     |
| - % of declared value                  |                  | 99.1             |     | 96.6   |     | 99.0   |     | 97.1                 |     | 101.2             |     | 97.1   |     | 98.5   |     | 98.0   |     | 98.7   |     |     |     |
| - % of initial value                   |                  | 100.0            |     | 97.5   |     | 99.9   |     | 98.0                 |     | 102.1             |     | 98.0   |     | 99.4   |     | 98.9   |     | 99.6   |     |     |     |
| Impurities (HPLC):                     |                  |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - Triazolnitrile (E#401) (%)           |                  | 0.06             |     | 0.06   |     | 0.06   |     | 0.06                 |     | 0.06              |     | 0.06   |     | 0.06   |     | 0.07   |     | 0.07   |     |     |     |
| - Anastrocol (E/406) (%)               |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Anastrochloride (E/407) (%)          |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Largest unspecified impurity (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total unspecified impurities (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05 |     |     |     |
| - Total impurities (%)                 |                  | 0.06             |     | 0.06   |     | 0.06   |     | 0.06                 |     | 0.06              |     | 0.06   |     | 0.06   |     | 0.07   |     | 0.07   |     |     |     |
| Microbial contamination:               |                  |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |        |     |        |     |     |     |
| - Total aerobic microbial count (TAMC) |                  | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Total combined yeasts/moulds count   |                  | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     |     |     |
| - Escherichia coli                     |                  | C                |     | ---    |     | C      |     | ---                  |     | C                 |     | ---    |     | C      |     | C      |     | C      |     |     |     |

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3.2 HDPE Bulk container 20 L

In this part of the Stability Study Summary the stability data of the Anastrozole 1 mg film-coated tablets stored in HDPE Bulk container 20 L at 30°C / 65% RH are presented.

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|                                        |                  |                  |     |        |     |                      |     |                  |     |                 |  |
|----------------------------------------|------------------|------------------|-----|--------|-----|----------------------|-----|------------------|-----|-----------------|--|
| Product / strength:                    |                  | Anastrozole 1 mg |     |        |     | Packaged lot number: |     | 05G11IS G        |     |                 |  |
| Storage condition:                     |                  | 30 °C/65 % RH    |     |        |     | Batch size:          |     | 1,000,000        |     |                 |  |
| Study start date:                      |                  | 05-08-05         |     |        |     | Packaging site:      |     | Synthon Hispania |     |                 |  |
| Tests ↓                                | Time in months → | 0                |     | 6      |     | 12                   |     | 24               |     | 36              |  |
| Appearance:                            |                  | C                |     | C      |     | C                    |     | C                |     | STUDY COMPLETED |  |
| Water content (%):                     |                  | 5.3              |     | 4.7    |     | 4.8                  |     | 5.0              |     |                 |  |
| Dissolution (%):                       |                  | min              | avg | min    | avg | min                  | avg | min              | avg |                 |  |
| - in 15 minutes                        |                  | 97               | 99  | 99     | 100 | 91                   | 96  | 98               | 99  |                 |  |
| Identification (ANA)                   |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |
| - HPLC retention time                  |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |
| Assay (ANA)                            |                  | 0.99             |     | 0.99   |     | 1.00                 |     | 0.97             |     |                 |  |
| - HPLC (mg/tab)                        |                  | 98.7             |     | 98.8   |     | 99.7                 |     | 96.9             |     |                 |  |
| - % of declared value                  |                  | 100.0            |     | 100.1  |     | 101.0                |     | 98.2             |     |                 |  |
| - % of initial value                   |                  | 0.06             |     | 0.06   |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |
| Impurities (HPLC):                     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |
| - Triazonitrile (E#401) (%)            |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |
| - Anastrocol (E/406) (%)               |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |
| - Anastrochloride (E/407) (%)          |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |
| - Largest unspecified impurity (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |
| - Total unspecified impurities (%)     |                  | 0.06             |     | 0.06   |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |
| - Total impurities (%)                 |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |
| Microbial contamination:               |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |
| - Total aerobic microbial count (TAMC) |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |
| - Total combined yeasts/moulds count   |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |
| - Escherichia coli                     |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |

STUDY COMPLETED

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|                                        |                  |                  |     |        |     |                      |     |                  |     |                 |  |     |     |
|----------------------------------------|------------------|------------------|-----|--------|-----|----------------------|-----|------------------|-----|-----------------|--|-----|-----|
| Product / strength:                    |                  | Anastrozole 1 mg |     |        |     | Packaged lot number: |     | 05G14IS G        |     |                 |  |     |     |
| Storage condition:                     |                  | 30 °C/65 % RH    |     |        |     | Batch size:          |     | 1,000,000        |     |                 |  |     |     |
| Study start date:                      |                  | 05-08-05         |     |        |     | Packaging site:      |     | Synthon Hispania |     |                 |  |     |     |
| Tests ↓                                | Time in months → | 0                |     | 6      |     | 12                   |     | 24               |     | 36              |  |     |     |
| Appearance:                            |                  | C                |     | C      |     | C                    |     | C                |     | STUDY COMPLETED |  |     |     |
| Water content (%):                     |                  | 5.3              |     | 4.7    |     | 4.8                  |     | 4.9              |     |                 |  |     |     |
| Dissolution (%):                       |                  | min              | avg | min    | avg | min                  | avg | min              | avg |                 |  | min | avg |
| - in 15 minutes                        |                  | 94               | 96  | 97     | 99  | 96                   | 98  | 95               | 98  |                 |  |     |     |
| Identification (ANA)                   |                  |                  |     |        |     |                      |     |                  |     |                 |  |     |     |
| - HPLC retention time                  |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |     |     |
| Assay (ANA)                            |                  |                  |     |        |     |                      |     |                  |     |                 |  |     |     |
| - HPLC (mg/tab)                        |                  | 0.98             |     | 0.99   |     | 1.00                 |     | 0.96             |     |                 |  |     |     |
| - % of declared value                  |                  | 98.3             |     | 99.0   |     | 99.7                 |     | 96.1             |     |                 |  |     |     |
| - % of initial value                   |                  | 100.0            |     | 100.7  |     | 101.4                |     | 97.8             |     |                 |  |     |     |
| Impurities (HPLC):                     |                  |                  |     |        |     |                      |     |                  |     |                 |  |     |     |
| - Triazonitrile (E#401) (%)            |                  | 0.07             |     | 0.06   |     | 0.06                 |     | ≤ 0.05           |     |                 |  |     |     |
| - Anastrocol (E/406) (%)               |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |     |     |
| - Anastrochloride (E/407) (%)          |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |     |     |
| - Largest unspecified impurity (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |     |     |
| - Total unspecified impurities (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |                 |  |     |     |
| - Total impurities (%)                 |                  | 0.07             |     | 0.06   |     | 0.06                 |     | ≤ 0.05           |     |                 |  |     |     |
| Microbial contamination:               |                  |                  |     |        |     |                      |     |                  |     |                 |  |     |     |
| - Total aerobic microbial count (TAMC) |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |     |     |
| - Total combined yeasts/moulds count   |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |     |     |
| - Escherichia coli                     |                  | C                |     | C      |     | C                    |     | C                |     |                 |  |     |     |

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|                                        |                  |                  |     |        |     |                      |     |                  |     |     |     |                 |
|----------------------------------------|------------------|------------------|-----|--------|-----|----------------------|-----|------------------|-----|-----|-----|-----------------|
| Product / strength:                    |                  | Anastrozole 1 mg |     |        |     | Packaged lot number: |     | 05G19IS G        |     |     |     |                 |
| Storage condition:                     |                  | 30 °C/65 % RH    |     |        |     | Batch size:          |     | 1,000,000        |     |     |     |                 |
| Study start date:                      |                  | 05-08-05         |     |        |     | Packaging site:      |     | Synthon Hispania |     |     |     |                 |
| Tests ↓                                | Time in months → | 0                |     | 6      |     | 12                   |     | 24               |     | 36  |     | STUDY COMPLETED |
| Appearance:                            |                  | C                |     | C      |     | C                    |     | C                |     |     |     |                 |
| Water content (%):                     |                  | 5.3              |     | 4.8    |     | 4.8                  |     | 4.9              |     |     |     |                 |
| Dissolution (%):                       |                  | min              | avg | min    | avg | min                  | avg | min              | avg | min | avg |                 |
| - in 15 minutes                        |                  | 92               | 96  | 95     | 98  | 96                   | 98  | 95               | 98  |     |     |                 |
| Identification (ANA)                   |                  |                  |     |        |     |                      |     |                  |     |     |     |                 |
| - HPLC retention time                  |                  | C                |     | C      |     | C                    |     | C                |     |     |     |                 |
| Assay (ANA)                            |                  |                  |     |        |     |                      |     |                  |     |     |     |                 |
| - HPLC (mg/tab)                        |                  | 0.99             |     | 0.99   |     | 0.99                 |     | 0.98             |     |     |     |                 |
| - % of declared value                  |                  | 99.1             |     | 99.0   |     | 99.3                 |     | 97.6             |     |     |     |                 |
| - % of initial value                   |                  | 100.0            |     | 99.9   |     | 100.2                |     | 98.5             |     |     |     |                 |
| Impurities (HPLC):                     |                  |                  |     |        |     |                      |     |                  |     |     |     |                 |
| - Triazonitrile (E#401) (%)            |                  | 0.06             |     | 0.06   |     | 0.06                 |     | 0.06             |     |     |     |                 |
| - Anastrocol (E/406) (%)               |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |     |     |                 |
| - Anastrochloride (E/407) (%)          |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05           |     |     |     |                 |
| - Largest unspecified impurity (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | 0.18                 |     | ≤ 0.05           |     |     |     |                 |
| - Total unspecified impurities (%)     |                  | ≤ 0.05           |     | ≤ 0.05 |     | 0.18                 |     | ≤ 0.05           |     |     |     |                 |
| - Total impurities (%)                 |                  | 0.06             |     | 0.06   |     | 0.24                 |     | 0.06             |     |     |     |                 |
| Microbial contamination:               |                  |                  |     |        |     |                      |     |                  |     |     |     |                 |
| - Total aerobic microbial count (TAMC) |                  | C                |     | C      |     | C                    |     | C                |     |     |     |                 |
| - Total combined yeasts/moulds count   |                  | C                |     | C      |     | C                    |     | C                |     |     |     |                 |
| - Escherichia coli                     |                  | C                |     | C      |     | C                    |     | C                |     |     |     |                 |

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4 Overview accelerated stability data 40 °C / 75 % RH

4.1 PVC/PE/PVDC/Aluminium blister

In this part of the Stability Study Summary the stability data of the Anastrozole 1 mg film-coated tablets stored in PVC/PE/PVDC/Al blister at 40°C / 75% RH are presented.

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|                                    |  |                  |  |                  |  |        |  |                      |  |        |  |                   |  |        |  |        |  |     |  |
|------------------------------------|--|------------------|--|------------------|--|--------|--|----------------------|--|--------|--|-------------------|--|--------|--|--------|--|-----|--|
| Product / strength:                |  |                  |  | Anastrozole 1 mg |  |        |  | Packaged lot number: |  |        |  | 05G11IS F         |  |        |  |        |  |     |  |
| Storage condition:                 |  |                  |  | 40 °C/75 % RH    |  |        |  | Batch size:          |  |        |  | 1,000,000 tablets |  |        |  |        |  |     |  |
| Study start date:                  |  |                  |  | 05-08-05         |  |        |  | Packaging site:      |  |        |  | Synthon Hispania  |  |        |  |        |  |     |  |
| Tests ↓                            |  | Time in months → |  | 0                |  | 1      |  | 2                    |  | 3      |  | 6                 |  | 9      |  | 12     |  |     |  |
| Appearance:                        |  |                  |  | C                |  | C      |  | C                    |  | C      |  | C                 |  | C      |  | C      |  |     |  |
| Water content (%):                 |  |                  |  | 5.3              |  | 5.3    |  | 6.0                  |  | 5.9    |  | 5.2               |  | 5.8    |  | 6.0    |  |     |  |
| Dissolution (%):                   |  |                  |  | min              |  | avg    |  | min                  |  | avg    |  | min               |  | avg    |  | min    |  | avg |  |
| - in 15 minutes                    |  |                  |  | 97               |  | 99     |  | 99                   |  | 100    |  | 96                |  | 99     |  | 92     |  | 96  |  |
| Identification (ANA)               |  |                  |  |                  |  |        |  |                      |  |        |  |                   |  |        |  |        |  |     |  |
| - HPLC retention time              |  |                  |  | C                |  | C      |  | C                    |  | C      |  | C                 |  | C      |  | C      |  |     |  |
| Assay (ANA)                        |  |                  |  |                  |  |        |  |                      |  |        |  |                   |  |        |  |        |  |     |  |
| - HPLC (mg/tab)                    |  |                  |  | 0.99             |  | 0.99   |  | 0.98                 |  | 0.97   |  | 1.01              |  | 1.00   |  | 0.99   |  |     |  |
| - % of declared value              |  |                  |  | 98.7             |  | 98.7   |  | 98.4                 |  | 97.3   |  | 101.0             |  | 99.8   |  | 99.2   |  |     |  |
| - % of initial value               |  |                  |  | 100.0            |  | 100.0  |  | 99.7                 |  | 98.6   |  | 102.3             |  | 101.1  |  | 100.5  |  |     |  |
| Impurities (HPLC):                 |  |                  |  |                  |  |        |  |                      |  |        |  |                   |  |        |  |        |  |     |  |
| - Triazolomitrile (E#401) (%)      |  |                  |  | 0.06             |  | 0.06   |  | 0.06                 |  | 0.06   |  | 0.06              |  | 0.06   |  | 0.06   |  |     |  |
| - Anastrocol (E/406) (%)           |  |                  |  | ≤ 0.05           |  | ≤ 0.05 |  | ≤ 0.05               |  | ≤ 0.05 |  | ≤ 0.05            |  | ≤ 0.05 |  | ≤ 0.05 |  |     |  |
| - Anastrochloride (E/407) (%)      |  |                  |  | ≤ 0.05           |  | ≤ 0.05 |  | ≤ 0.05               |  | ≤ 0.05 |  | ≤ 0.05            |  | ≤ 0.05 |  | ≤ 0.05 |  |     |  |
| - Largest unspecified impurity (%) |  |                  |  | ≤ 0.05           |  | 0.06   |  | ≤ 0.05               |  | ≤ 0.05 |  | ≤ 0.05            |  | 0.06   |  | ≤ 0.05 |  |     |  |
| - Total unspecified impurities (%) |  |                  |  | ≤ 0.05           |  | 0.06   |  | ≤ 0.05               |  | ≤ 0.05 |  | ≤ 0.05            |  | 0.06   |  | ≤ 0.05 |  |     |  |
| - Total impurities (%)             |  |                  |  | 0.06             |  | 0.12   |  | 0.06                 |  | 0.06   |  | 0.06              |  | 0.12   |  | 0.06   |  |     |  |
| Study completed                    |  |                  |  |                  |  |        |  |                      |  |        |  |                   |  |        |  |        |  |     |  |

Study completed

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|                                    |                  |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |                 |
|------------------------------------|------------------|------------------|-----|--------|-----|--------|-----|----------------------|-----|-------------------|-----|--------|-----|--------|-----|-----------------|
| Container:                         |                  | Anastrozole 1 mg |     |        |     |        |     | Packaged lot number: |     | 05G14IS F         |     |        |     |        |     |                 |
| Storage condition:                 |                  | 40°C/75 % RH     |     |        |     |        |     | Batch size:          |     | 1.000.000 tablets |     |        |     |        |     |                 |
| Study start date:                  |                  | 05-08-05         |     |        |     |        |     | Packaging site:      |     | Synthon Hispania  |     |        |     |        |     |                 |
| Tests ↓                            | Time in months → | 0                |     | 1      |     | 2      |     | 3                    |     | 6                 |     | 9      |     | 12     |     | Study completed |
| Appearance:                        |                  | C                |     | C      |     | C      |     | C                    |     | C                 |     | C      |     | C      |     |                 |
| Water content (%):                 |                  | 5.3              |     | 5.5    |     | 6.0    |     | 5.9                  |     | 5.1               |     | 5.8    |     | 6.2    |     |                 |
| Dissolution (%):                   |                  | min              | avg | min    | avg | min    | avg | min                  | avg | min               | avg | min    | avg | min    | avg |                 |
| - in 15 minutes                    |                  | 94               | 96  | 91     | 96  | 93     | 97  | 90                   | 93  | 94                | 96  | 85     | 92  | 88     | 93  |                 |
| Identification (ANA)               |                  |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |                 |
| - HPLC retention time              |                  | C                |     | C      |     | C      |     | C                    |     | C                 |     | C      |     | C      |     |                 |
| Assay (ANA)                        |                  |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |                 |
| - HPLC (mg/tab)                    |                  | 0.98             |     | 0.98   |     | 0.98   |     | 0.97                 |     | 0.99              |     | 0.98   |     | 0.99   |     |                 |
| - % of declared value              |                  | 98.3             |     | 97.5   |     | 97.7   |     | 96.6                 |     | 98.6              |     | 97.6   |     | 98.8   |     |                 |
| - % of initial value               |                  | 100.0            |     | 99.2   |     | 99.4   |     | 98.3                 |     | 100.3             |     | 99.3   |     | 100.5  |     |                 |
| Impurities (HPLC):                 |                  |                  |     |        |     |        |     |                      |     |                   |     |        |     |        |     |                 |
| - Triazonitrile (E#401) (%)        |                  | 0.07             |     | 0.06   |     | 0.06   |     | 0.06                 |     | 0.06              |     | 0.06   |     | 0.06   |     |                 |
| - Anastrocol (E/406) (%)           |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     |                 |
| - Anastrochloride (E/407) (%)      |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | ≤ 0.05 |     | ≤ 0.05 |     |                 |
| - Largest unspecified impurity (%) |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | 0.06   |     | ≤ 0.05 |     |                 |
| - Total unspecified impurities (%) |                  | ≤ 0.05           |     | ≤ 0.05 |     | ≤ 0.05 |     | ≤ 0.05               |     | ≤ 0.05            |     | 0.06   |     | ≤ 0.05 |     |                 |
| - Total impurities (%)             |                  | 0.07             |     | 0.06   |     | 0.06   |     | 0.06                 |     | 0.06              |     | 0.11   |     | 0.06   |     |                 |

Study completed

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|                                    |                  |                  |        |        |        |                      |        |                   |                 |  |     |
|------------------------------------|------------------|------------------|--------|--------|--------|----------------------|--------|-------------------|-----------------|--|-----|
| Product / strength:                |                  | Anastrozole 1 mg |        |        |        | Packaged lot number: |        | 05G19IS F         |                 |  |     |
| Storage condition:                 |                  | 40 °C/75 % RH    |        |        |        | Batch size:          |        | 1,000,000 tablets |                 |  |     |
| Study start date:                  |                  | 05-08-05         |        |        |        | Packaging site:      |        | Synthon Hispania  |                 |  |     |
| Tests ↓                            | Time in months → | 0                | 1      | 2      | 3      | 6                    | 9      | 12                | Study completed |  |     |
| Appearance:                        |                  | C                | C      | C      | C      | C                    | C      | C                 |                 |  |     |
| Water content (%):                 |                  | 5.3              | 5.2    | 5.9    | 5.2    | 5.6                  | 5.8    | 5.9               |                 |  |     |
| Dissolution (%):                   |                  | min              | avg    | min    | avg    | min                  | avg    | min               |                 |  | avg |
| - in 15 minutes                    |                  | 92               | 96     | 93     | 98     | 92                   | 96     | 84                |                 |  | 90  |
| Identification (ANA)               |                  |                  |        |        |        |                      |        |                   |                 |  |     |
| - HPLC retention time              |                  | C                | C      | C      | C      | C                    | C      | C                 |                 |  |     |
| Assay (ANA)                        |                  |                  |        |        |        |                      |        |                   |                 |  |     |
| - HPLC (mg/tab)                    |                  | 0.99             | 0.98   | 0.98   | 0.97   | 1.01                 | 0.98   | 1.04              |                 |  |     |
| - % of declared value              |                  | 99.1             | 97.9   | 98.0   | 96.5   | 100.5                | 97.7   | 104.0             |                 |  |     |
| - % of initial value               |                  | 100.0            | 98.8   | 98.9   | 97.4   | 101.4                | 98.6   | 105.0             |                 |  |     |
| Impurities (HPLC):                 |                  |                  |        |        |        |                      |        |                   |                 |  |     |
| - Triazolnitrile (E#401) (%)       |                  | 0.06             | 0.07   | 0.06   | 0.07   | 0.06                 | 0.06   | 0.06              |                 |  |     |
| - Anastrocol (E/406) (%)           |                  | ≤ 0.05           | ≤ 0.05 | ≤ 0.05 | ≤ 0.05 | ≤ 0.05               | ≤ 0.05 | ≤ 0.05            |                 |  |     |
| - Anastrochloride (E/407) (%)      |                  | ≤ 0.05           | ≤ 0.05 | ≤ 0.05 | ≤ 0.05 | ≤ 0.05               | ≤ 0.05 | ≤ 0.05            |                 |  |     |
| - Largest unspecified impurity (%) |                  | ≤ 0.05           | ≤ 0.05 | ≤ 0.05 | ≤ 0.05 | ≤ 0.05               | 0.06   | ≤ 0.05            |                 |  |     |
| - Total unspecified impurities (%) |                  | ≤ 0.05           | ≤ 0.05 | ≤ 0.05 | ≤ 0.05 | ≤ 0.05               | 0.06   | ≤ 0.05            |                 |  |     |
| - Total impurities (%)             |                  | 0.06             | 0.07   | 0.06   | 0.07   | 0.06                 | 0.12   | 0.06              |                 |  |     |

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5 Photostability

In this part of the Stability Study Summary the stability data of the Anastrozole 1 mg film-coated tablets, bare product on open dish, exposed to light conditions, which correspond to a light exposure of 200 Watt hours/m<sup>2</sup> and 1.2 million lux hours respectively, are presented.

|                                    |                  |                                    |     |           |     |                      |     |                 |  |
|------------------------------------|------------------|------------------------------------|-----|-----------|-----|----------------------|-----|-----------------|--|
| Product / strength:                |                  | Anastrozole 1 mg                   |     |           |     | Packaged lot number: |     | 05G11IS F       |  |
| Storage condition:                 |                  | Directly exposed (on a Petri dish) |     |           |     | Batch size:          |     | NA              |  |
| Study start date:                  |                  | 17/10/05                           |     |           |     |                      |     |                 |  |
| Tests ↓                            | Time in months → | 0                                  |     | 200 Wh/m2 |     | 1.2 Mlux h           |     |                 |  |
| Appearance:                        |                  | C                                  |     | C         |     | C                    |     | Study completed |  |
| Water content (%):                 |                  | 5.4                                |     | 5.8       |     | 5.6                  |     |                 |  |
| Dissolution (%):                   |                  | min                                | avg | min       | avg | min                  | avg |                 |  |
| - in 15 minutes                    |                  | 96                                 | 100 | 95        | 97  | 96                   | 99  |                 |  |
| Identification (ANA)               |                  |                                    |     |           |     |                      |     |                 |  |
| - HPLC retention time              |                  | C                                  |     | C         |     | C                    |     |                 |  |
| Assay (ANA)                        |                  |                                    |     |           |     |                      |     |                 |  |
| - HPLC (mg/tab)                    |                  | 0.98                               |     | 1.00      |     | 0.99                 |     |                 |  |
| - % of declared value              |                  | 98.5                               |     | 99.5      |     | 98.5                 |     |                 |  |
| - % of initial value               |                  | 100.0                              |     | 101.0     |     | 100.0                |     |                 |  |
| Impurities (HPLC):                 |                  |                                    |     |           |     |                      |     |                 |  |
| - Triazonitrile (E#401) (%)        |                  | 0.06                               |     | 0.06      |     | 0.06                 |     |                 |  |
| - Anastrocol (E/406) (%)           |                  | ≤ 0.05                             |     | ≤ 0.05    |     | ≤ 0.05               |     |                 |  |
| - Anastrochloride (E/407) (%)      |                  | ≤ 0.05                             |     | ≤ 0.05    |     | ≤ 0.05               |     |                 |  |
| - Largest unspecified impurity (%) |                  | ≤ 0.05                             |     | ≤ 0.05    |     | ≤ 0.05               |     |                 |  |
| - Total unspecified impurities (%) |                  | ≤ 0.05                             |     | ≤ 0.05    |     | ≤ 0.05               |     |                 |  |
| - Total impurities (%)             |                  | 0.06                               |     | 0.06      |     | 0.06                 |     |                 |  |