



Office of The Commissioner,  
Food & Drugs Administration M.S.  
Bandra – Kurla Complex,  
Bandra (E),  
Mumbai – 400 051

Date : 2/8/2017.

### CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.

(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/KD/58898/2017/11/20290**

On the basis of the inspection carried out on 19/06/2017, 20/06/2017 and 26/07/2017, we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **CENTAUR PHARMACEUTICALS PRIVATE LIMITED.**  
Address : **PLOT NO. 75, 76 & 76/1 CHIKHLOLI MIDC, AMBERNATH (WEST), THANE 421501 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD1149 In Form 25, KD6 In Form 25F**

Table 1

| Sr.No. | Dosage Form(s)                                  | Categor(ies)                                                           | Activity(ies)                                                                   |
|--------|-------------------------------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| 1      | Active Pharmaceutical Ingredients ( Bulk Drugs) | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance |

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 01 Aug 2019 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :  
Food & Drug Administration, M.S.  
Bandra-kurla Complex,  
Bandra (E), Mumbai – 400 051,  
Maharashtra, INDIA.  
Tel: +91-22-26592363/24  
Fax: +91-22-26591953  
1NEC555889820170802

Name of the Authorised person : **O S SADHWANI**

Signature : 

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**  
Food & Drug Administration, M.S.  
Bandra (E), Mumbai.  
Maharashtra State, India  
Date: 02 Aug 2017



02 AUG 2017.

### Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a licence for the site, this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.
4. Table 1  
List the dosage forms, starting materials, categories and activities. Examples are given below.

#### Example -1

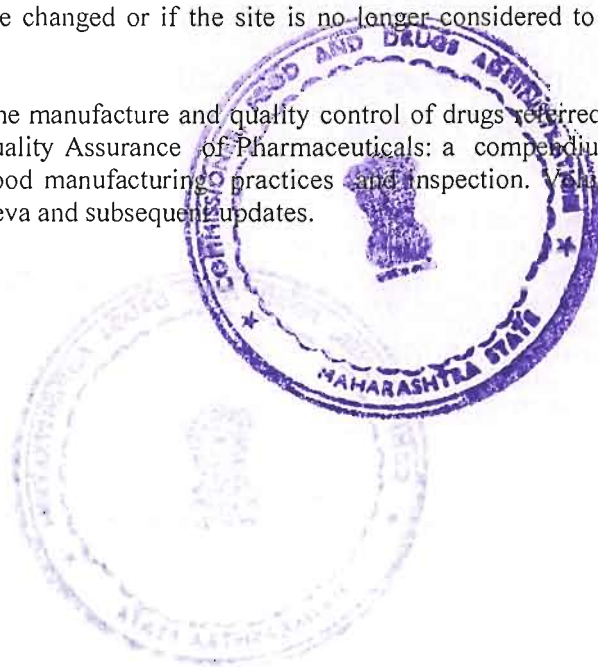
| Pharmaceutical Product (s) <sup>1</sup> | Category (ies)       | Activity (ies)                                       |
|-----------------------------------------|----------------------|------------------------------------------------------|
| Dosage form (s)                         |                      |                                                      |
| Tablets                                 | Cytotoxic<br>Hormone | Packaging<br>Production, Packaging, Quality control. |
| Injectables                             | Penicillin           | Repackaging & Labelling.                             |
|                                         | Cefalosporin         | Aseptic preparation, Packaging, Labelling.           |

#### Example - 2.

| Pharmaceutical Product (s) <sup>1</sup> | Category (ies) | Activity (ies)                                  |
|-----------------------------------------|----------------|-------------------------------------------------|
| Starting material (s) <sup>2</sup>      |                |                                                 |
| Paracetamol                             | Analgesic      | Synthesis, Purification,<br>Packing, Labelling. |

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



# LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>

No. of certificate : NEW-WHO-GMP/CERT/KD/58898/2017/11 VALID UP TO :01 Aug 2019 /20290

Name of Manufacrting Firm : CENTAUR PHARMACEUTICALS PRIVATE LIMITED.  
PLOT NO. 75, 76 & 76/1 CHIKHLOLI MIDC,  
AMBERNATH (WEST), THANE 421501  
MAHARASHTRA STATE, INDIA

Drug License No : KD1149 In Form 25, KD6  
In Form 25F

| Sr.No.                   | Name of the Product | Composition |
|--------------------------|---------------------|-------------|
| 1                        | ALPRAZOLAM BP       |             |
| 2                        | ALPRAZOLAM EP       |             |
| 3                        | ALPRAZOLAM IP       |             |
| 4                        | ALPRAZOLAM JP       |             |
| 5                        | ALPRAZOLAM USP      |             |
| 6                        | ARIPIPRAZOLE BP     |             |
| 7                        | Aripiprazole EP     |             |
| 8                        | ARIPIPRAZOLE IP     |             |
| 1 2 3 4 5 6 7 8 9 10 ... |                     |             |



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Name of the Authorised person : O S SADHWANI

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority  
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| Sr.No. | Name of the Product          | Composition |
|--------|------------------------------|-------------|
| 9      | ARIPIRAZOLE USP              |             |
| 10     | BENZYLAMINE HYDROCHLORIDE BP |             |
| 11     | BRIMONIDINE TARTRATE BP      |             |
| 12     | Brimonidine Tartrate EP      |             |
| 13     | BRIMONIDINE TARTRATE IP      |             |
| 14     | BROMAZEPAM BP                |             |
| 15     | BROMAZEPAM IP                |             |
| 16     | BROMAZEPAM JP                |             |



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| Sr.No.                   | Name of the Product             | Composition |
|--------------------------|---------------------------------|-------------|
| 17                       | BROTIZOLAM EP                   |             |
| 18                       | CHLORDIAZEPOXIDE BP             |             |
| 19                       | CHLORDIAZEPOXIDE EP             |             |
| 20                       | CHLORDIAZEPOXIDE IP             |             |
| 21                       | CHLORDIAZEPOXIDE JP             |             |
| 22                       | CHLORDIAZEPOXIDE USP            |             |
| 23                       | CHLOROPYRAMINE<br>HYDROCHLORIDE |             |
| 24                       | CLOBAZAM BP                     |             |
| 1 2 3 4 5 6 7 8 9 10 ... |                                 |             |



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| Sr.No. | Name of the Product | Composition |
|--------|---------------------|-------------|
| 25     | CLOBAZAM EP         |             |
| 26     | CLOBAZAM IP         |             |
| 27     | CLONAZEPAM BP       |             |
| 28     | CLONAZEPAM EP       |             |
| 29     | CLONAZEPAM IP       |             |
| 30     | CLONAZEPAM USP      |             |
| 31     | CLOTIAZEPAM JP      |             |
| 32     | DELORAZEPAM         |             |



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| Sr.No. | Name of the Product | Composition |
|--------|---------------------|-------------|
| 33     | DIAZEPAM BP         |             |
| 34     | DIAZEPAM EP         |             |
| 35     | DIAZEPAM IP         |             |
| 36     | DIAZEPAM JP         |             |
| 37     | DIAZEPAM USP        |             |
| 38     | Estazolam           |             |
| 39     | ES-ZOPICLONE        |             |
| 40     | ESZOPICLONE USP     |             |



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| Sr.No. | Name of the Product               | Composition |
|--------|-----------------------------------|-------------|
| 41     | ETIZOLAM JP                       |             |
| 42     | FLUDIAZEPAM                       |             |
| 43     | FLUPENTIXOL DIHYDROCHLORIDE<br>BP |             |
| 44     | FLUPENTIXOL DIHYDROCHLORIDE<br>EP |             |
| 45     | FLUPHENAZINE HYDROCHLORIDE<br>BP  |             |
| 46     | FLUPHENAZINE HYDROCHLORIDE<br>EP  |             |
| 47     | FLUPHENAZINE HYDROCHLORIDE IP     |             |
| 48     | FLUPHENAZINE HYDROCHLORIDE<br>USP |             |



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| Sr.No. | Name of the Product                | Composition |
|--------|------------------------------------|-------------|
| 49     | FLURAZEPAM<br>MONOHYDROCHLORIDE BP |             |
| 50     | FLURAZEPAM<br>MONOHYDROCHLORIDE EP |             |
| 51     | LORAZEPAM BP                       |             |
| 52     | LORAZEPAM EP                       |             |
| 53     | LORAZEPAM IP                       |             |
| 54     | LORAZEPAM JP                       |             |
| 55     | LORAZEPAM USP                      |             |
| 56     | Lormetazepam BP                    |             |



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| Sr.No. | Name of the Product                  | Composition |
|--------|--------------------------------------|-------------|
| 57     | LOXAPINE SUCCINATE USP               |             |
| 58     | MELITRACEN HYDROCHLORIDE             |             |
| 59     | METHYLPHENIDATE<br>HYDROCHLORIDE BP  |             |
| 60     | METHYLPHENIDATE<br>HYDROCHLORIDE EP  |             |
| 61     | METHYLPHENIDATE<br>HYDROCHLORIDE IP  |             |
| 62     | METHYLPHENIDATE<br>HYDROCHLORIDE USP |             |
| 63     | METOLAZONE BP                        |             |
| 64     | METOLAZONE EP                        |             |



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MAHARASHTRA STATE, INDIA  
Drug License No : KDI149 In Form 25, KD6  
In Form 25F

| Sr.No. | Name of the Product     | Composition |
|--------|-------------------------|-------------|
| 65     | METOLAZONE IP           |             |
| 66     | METOLAZONE USP          |             |
| 67     | METOPIMAZINE            |             |
| 68     | MIDAZOLAM BP            |             |
| 69     | MIDAZOLAM EP            |             |
| 70     | MIDAZOLAM HYDROCHLORIDE |             |
| 71     | MIDAZOLAM IP            |             |
| 72     | MIDAZOLAM MALEATE       |             |



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| Sr.No.                   | Name of the Product | Composition |
|--------------------------|---------------------|-------------|
| 73                       | MIDAZOLAM USP       |             |
| 74                       | MILNACIPRAN HCL     |             |
| 75                       | NABILONE            |             |
| 76                       | NIMORAZOLE          |             |
| 77                       | NITRAZEPAM BP       |             |
| 78                       | NITRAZEPAM EP       |             |
| 79                       | NITRAZEPAM IP       |             |
| 80                       | NITRAZEPAM JP       |             |
| 1 2 3 4 5 6 7 8 9 10 ... |                     |             |



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| Sr.No.                        | Name of the Product                | Composition |
|-------------------------------|------------------------------------|-------------|
| 81                            | NORTRIPTYLINE HYDROCHLORIDE<br>BP  |             |
| 82                            | NORTRIPTYLINE HYDROCHLORIDE<br>EP  |             |
| 83                            | NORTRIPTYLINE HYDROCHLORIDE<br>IP  |             |
| 84                            | NORTRIPTYLINE HYDROCHLORIDE<br>JP  |             |
| 85                            | NORTRIPTYLINE HYDROCHLORIDE<br>USP |             |
| 86                            | OLOPATADINE HYDROCHLORIDE<br>USP   |             |
| 87                            | OXAZEPAM BP                        |             |
| 88                            | OXAZEPAM EP                        |             |
| ... 6 7 8 9 10 11 12 13 14 15 |                                    |             |



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| Sr.No. | Name of the Product               | Composition |
|--------|-----------------------------------|-------------|
| 89     | OXAZEPAM IP                       |             |
| 90     | OXAZEPAM USP                      |             |
| 91     | PITOFENONE HYDROCHLORIDE          |             |
| 92     | PRAZEPAM EP                       |             |
| 93     | PRAZEPAM JP                       |             |
| 94     | PROPIVERINE HYDROCHLORIDE JP      |             |
| 95     | REBAMIPIDE IP                     |             |
| 96     | RIVASTIGMINE HYDROGEN<br>TARTRATE |             |



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| Sr.No.                                                                                              | Name of the Product                               | Composition |
|-----------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------|
| 97                                                                                                  | SODIUM OXYBATE (GAMMA<br>HYDROXY BUTYRATE SODIUM) |             |
| 98                                                                                                  | TEMAZEPAM BP                                      |             |
| 99                                                                                                  | TEMAZEPAM EP                                      |             |
| 100                                                                                                 | TEMAZEPAM USP                                     |             |
| 101                                                                                                 | TETRABENAZINE                                     |             |
| 102                                                                                                 | TIEMONIUM METHYL SULFATE                          |             |
| 103                                                                                                 | TIMOLOL MALEATE BP                                |             |
| 104                                                                                                 | TIMOLOL MALEATE EP                                |             |
| ... <u>6</u> <u>7</u> <u>8</u> <u>9</u> <u>10</u> <u>11</u> <u>12</u> <u>13</u> <u>14</u> <u>15</u> |                                                   |             |



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Date:02 Aug 2017

02 AUG 2017

# LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>

No. of certificate : NEW-WHO-GMP/CERT/KD/58898/2017/11 VALID UP TO :01 Aug 2019  
/20290  
Name of Manufacturing Firm : CENTAUR PHARMACEUTICALS  
PRIVATE LIMITED.  
PLOT NO. 75, 76 & 76/I CHIKHLOLI MIDC,  
AMBERNATH (WEST), THANE 421501  
MAHARASHTRA STATE, INDIA  
Drug License No : KD1149 In Form 25, KD6  
In Form 25F

| Sr.No. | Name of the Product          | Composition |
|--------|------------------------------|-------------|
| 105    | TIMOLOL MALEATE IP           |             |
| 106    | TIMOLOL MALEATE JP           |             |
| 107    | TIMOLOL MALEATE USP          |             |
| 108    | TRANLYCYPROMINE SULPHATE BP  |             |
| 109    | TRANLYCYPROMINE SULPHATE USP |             |
| 110    | TRIAZOLAM USP                |             |
| 111    | ZALEPLON USP                 |             |
| 112    | ZOLPIDEM TARTRATE BP         |             |



... 6 7 8 9 10 11 12 13 14 15

Address of certifying authority :  
Food & Drug Administration, M.S.  
Dandra-kurta Complex,  
Bandra (E), Mumbai - 400 051.  
Maharashtra, INDIA.  
Tel: +91-22-26592363/64  
Fax: +91-22-26591959  
1NEC555889820170802

Name of the Authorised person : O S SADHWANI

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority  
Food & Drug Administration, M.S.  
Bandra (E), Mumbai.  
Maharashtra State, India  
Date:02 Aug 2017

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In Form 25F

| Sr.No. | Name of the Product   | Composition |
|--------|-----------------------|-------------|
| 113    | ZOLPIDEM TARTRATE EP  |             |
| 114    | ZOLPIDEM TARTRATE IP  |             |
| 115    | ZOLPIDEM TARTRATE JP  |             |
| 116    | ZOLPIDEM TARTRATE USP |             |
| 117    | ZOPICLONE BP          |             |
| 118    | ZOPICLONE EP          |             |
| 119    | ZOPICLONE IP          |             |



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