



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

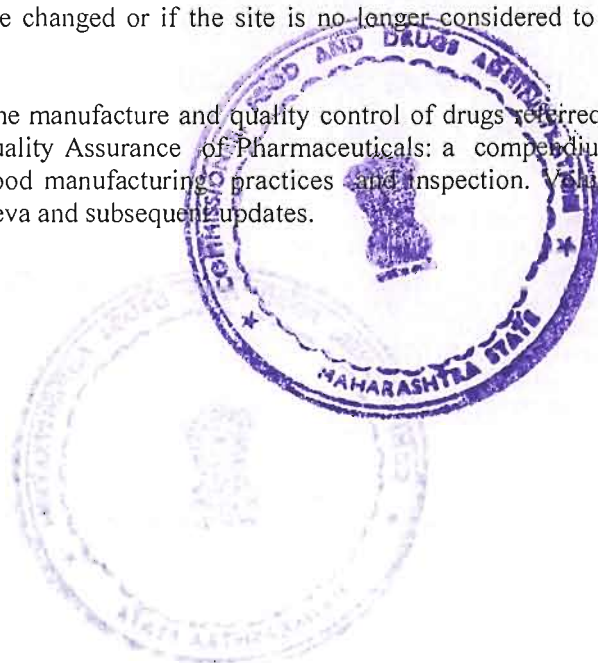
Pharmaceutical Product (s) ₁	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic Hormone	Packaging Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product (s) ₁	Category (ies)	Activity (ies)
Starting material (s) ₂		
Paracetamol	Analgesic	Synthesis, Purification, 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 GMP¹

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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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 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 BP	
44	FLUPENTIXOL DIHYDROCHLORIDE EP	
45	FLUPHENAZINE HYDROCHLORIDE BP	
46	FLUPHENAZINE HYDROCHLORIDE EP	
47	FLUPHENAZINE HYDROCHLORIDE IP	
48	FLUPHENAZINE HYDROCHLORIDE USP	



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Drug License No : KDI149 In Form 25, KD6
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Sr.No.	Name of the Product	Composition
49	FLURAZEPAM MONOHYDROCHLORIDE BP	
50	FLURAZEPAM 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 HYDROCHLORIDE BP	
60	METHYLPHENIDATE HYDROCHLORIDE EP	
61	METHYLPHENIDATE HYDROCHLORIDE IP	
62	METHYLPHENIDATE HYDROCHLORIDE USP	
63	METOLAZONE BP	
64	METOLAZONE EP	



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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	



1 2 3 4 5 6 7 8 9 10 ...

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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 BP	
82	NORTRIPTYLINE HYDROCHLORIDE EP	
83	NORTRIPTYLINE HYDROCHLORIDE IP	
84	NORTRIPTYLINE HYDROCHLORIDE JP	
85	NORTRIPTYLINE HYDROCHLORIDE USP	
86	OLOPATADINE HYDROCHLORIDE 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 TARTRATE	



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

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Sr.No.	Name of the Product	Composition
97	SODIUM OXYBATE (GAMMA 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	



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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	



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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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