



We Impart Health to Life

CENTAUR PHARMACEUTICALS PVT. LTD.

API DIVISION

Centaur House, Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E),
Mumbai - 400 055, INDIA. CIN - U24230MH1980PTC023291

Tel: +91 22 66499100 • Fax: +91 22 66499108/112

Email: export@centaurchem.com • Website: <http://www.centaurpharma.com/api>

Formulations • API • Contract Manufacturing • Contract Research

11/01/2021

Marianela Hechem

Regulatory Affairs Manager

Grupo Grünenthal Chile

Av. Quilín 5273, Peñalolén, Santiago, Chile.

TEL: +56225948683

Email: Marianela.Hechem@grunenthal.com

Dear Marianela,

Sub: Apostilled GMP Certificate.

As you requested therein, we are sending herewith duly apostilled GMP Certificate.

Kindly acknowledge receipt.

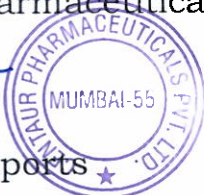
Yours Faithfully

For Centaur Pharmaceuticals Pvt. Ltd.

1

Prasanna
Revathi Poojary

Sr. Manager-Exports





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

14 OCT 2019

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/85796/2019/11/29756

On the basis of the inspection carried out on 05/07/2019, 06/07/2019 and 25/07/2019, 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 CHIKHOLI 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)	Category(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, Labelling, Quality Control, Quality Assurance
2	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 10 Oct 2022. 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: +91-22-26592363/64

Fax: +91-22-26591959

1NEC5558579620191011

CENTAUR PHARMACEUTICALS PRIVATE LIMITED.

NEW-WHO-GMP/CERT/KD/85796/2019/11/29756

Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai

Maharashtra State, India

Date: 11 Oct 2019



11 OCT 2019

A copy of this document / CERTIFICATE has been recorded with the Chamber

MR. SAMIR PAUL PINTO
ASSISTANT MANAGER



Authorized Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 30909 Date 21 OCT 2020



Explanatory notes

- This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
- The certification number should be traceable within the regulatory authority issuing the certificate.
 - 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.
 - Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example - 1

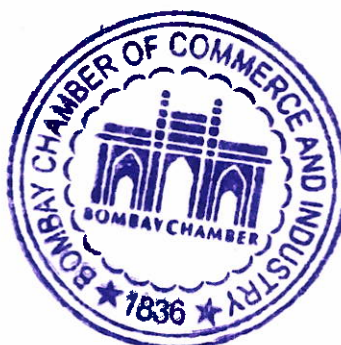
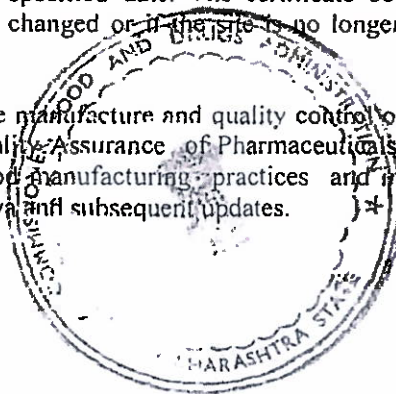
Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production. Packaging. Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

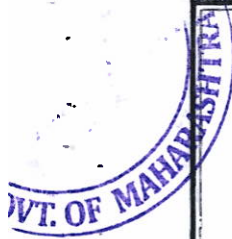
Example - 2.

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.

- 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.
- 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.



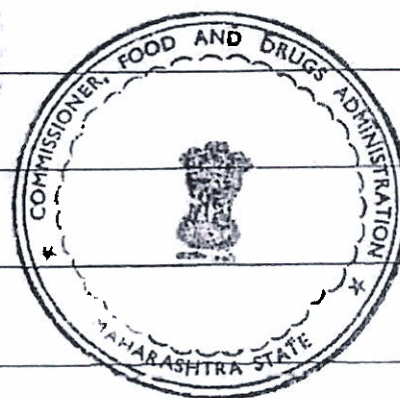
**LIST OF PRODUCT APPROVED UNDER WHO GMP¹**

No. of certificate : NEW-WHO-GMP/CERT/KD/85796/2019/11 VALID UP TO : 10 Oct 2022 /29756

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

Drug License No : KDI149 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	Amoxapine HSP	
7	ARIPIRAZOLE BP	
8	Aripiprazole EP	



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

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/29756

Name of the Authorised person : A. T. NIKHADE

Signature :

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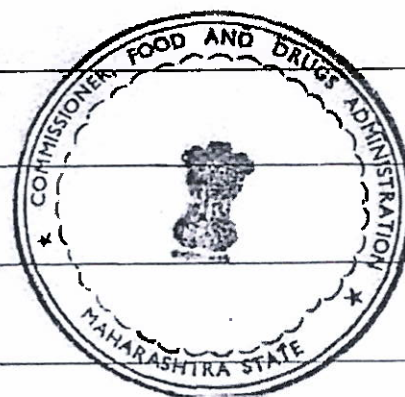
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MAHARASHTRA STATE, INDIA

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

Sr.No.	Name of the Product	Composition
9	ARIPIRAZOLE IP	
10	ARIPIRAZOLE USP	
11	BENZYLAMINE HYDROCHLORIDE BP	
12	BRIMONIDINE TARTRATE BP	
13	Brimonidine Tartrate EP	
14	BRIMONIDINE TARTRATE IP	
15	BRIMONIDINE TARTRATE USP	
16	BROMAZEPAM BP	



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Sr.No.	Name of the Product	Composition
17	BROMAZEPAM EP	
18	BROMAZEPAM JP	
19	BROTIZOLAM EP	
20	BROTIZOLAM JP	
21	CHLORDIAZEPOXIDE BP	
22	CHLORDIAZEPOXIDE EP	
23	CHLORDIAZEPOXIDE IP	
24	CHLORDIAZEPOXIDE JP	



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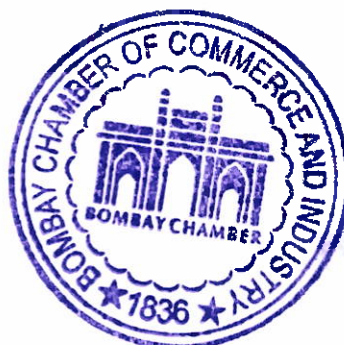
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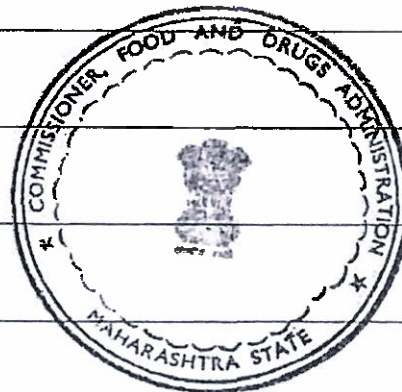
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 MAHARASHTRA STATE, INDIA
 Drug License No : KD1149 In Form 25, KD6
 In Form 25F

Sr.No.	Name of the Product	Composition
25	CHLORDIAZEPOXIDE USP	
26	CHLOROPYRAMINE HYDROCHLORIDE	
27	CHLORZOXAZONE USP	
28	CLOBAZAM BP	
29	CLOBAZAM EP	
30	CLOBAZAM IP	
31	CLONAZEPAM BP	
32	CLONAZEPAM EP	



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

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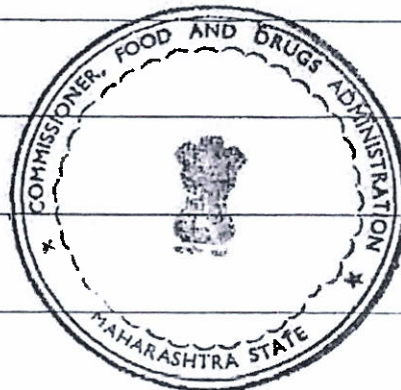
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MAHARASHTRA STATE, INDIA

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

Sr.No.	Name of the Product	Composition
33	CLONAZEPAM IP	
34	CLONAZEPAM USP	
35	CLOTIAZEPAM JP	
36	DELORAZEPAM	
37	DIAZEPAM BP	
38	DIAZEPAM EP	
39	DIAZEPAM IP	
40	DIAZEPAM JP	



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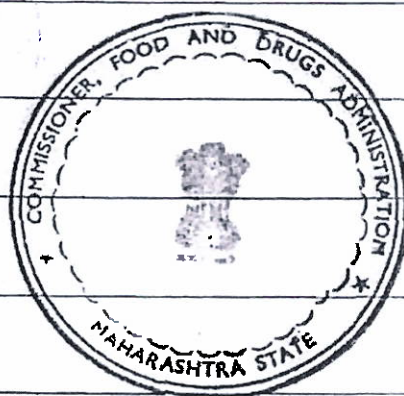
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MAHARASHTRA STATE, INDIA

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

Sr.No.	Name of the Product	Composition
41	DIAZEPAM USP	
42	ESTAZOLAM	
43	ES-ZOPICLONE	
44	ESZOPICLONE USP	
45	ETIZOLAM JP	
46	FAMPRIDINE	
47	FLUDIAZEPAM	
48	FLUPENTIXOL DIHYDROCHLORIDE BP	



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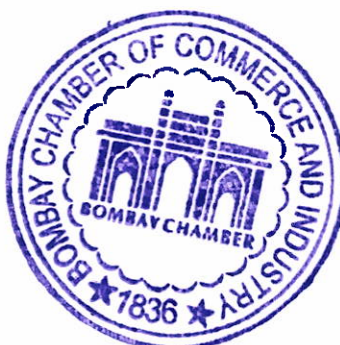
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MAHARASHTRA STATE, INDIA

Drug License No : KD1149 In Form 25, K06
In Form 25F

Sr.No.	Name of the Product	Composition
49	FLUPENTIXOL DIHYDROCHLORIDE EP	
50	FLUPHENAZINE HYDROCHLORIDE BP	
51	FLUPHENAZINE HYDROCHLORIDE EP	
52	FLUPHENAZINE HYDROCHLORIDE IP	
53	FLUPHENAZINE HYDROCHLORIDE USP	
54	FLURAZEPAM MONOHYDROCHLORIDE BP	
55	FLURAZEPAM MONOHYDROCHLORIDE EP	
56	LORAZEPAM BP	



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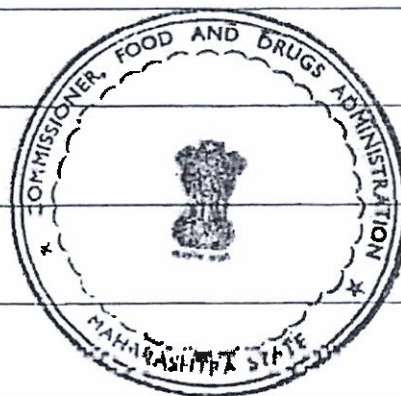
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AMBERNATH (WEST), THANE 421501
MAHARASHTRA STATE, INDIA
Drug License No : KD1149 In Form 25, KD6
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Sr.No.	Name of the Product	Composition
57	LORAZEPAM EP	
58	LORAZEPAM IP	
59	LORAZEPAM JP	
60	LORAZEPAM USP	
61	LORMETAZEPAM BP	
62	LOXAPINE SUCCINATE USP	
63	MELITRACEN HYDROCHLORIDE	
64	METHYLPHENIDATE HYDROCHLORIDE BP	



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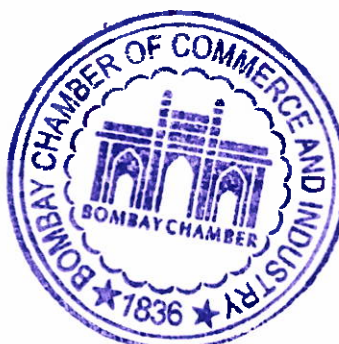
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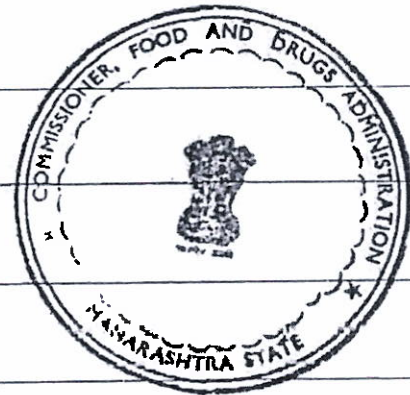
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MAHARASHTRA STATE, INDIA

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

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



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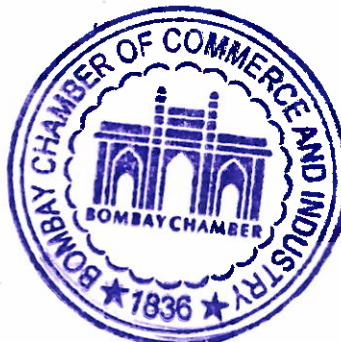
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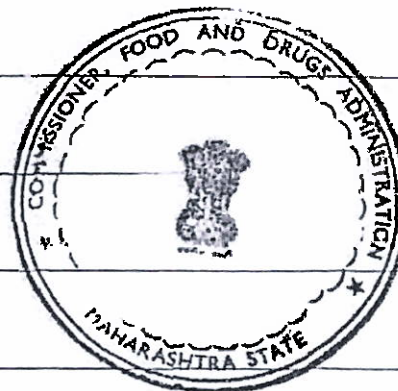
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MAHARASHTRA STATE, INDIA

Drug License No : KD1149 In Form 25, KD6
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Sr.No.	Name of the Product	Composition
73	MIDAZOLAM BP	
74	MIDAZOLAM EP	
75	MIDAZOLAM HYDROCHLORIDE	
76	MIDAZOLAM IP	
77	MIDAZOLAM MALEATE	
78	MIDAZOLAM USP	
79	MILNACIPRAN HCL	
80	NABILONE	



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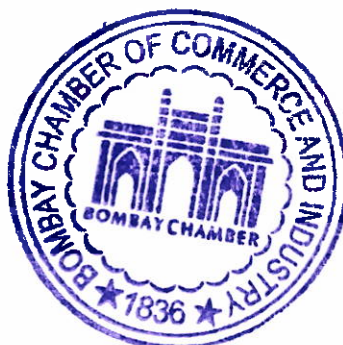
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Sr.No.	Name of the Product	Composition
81	NIMORAZOLE	
82	NITRAZEPAM BP	
83	NITRAZEPAM EP	
84	NITRAZEPAM IP	
85	NITRAZEPAM JP	
86	NORTRIPTYLINE HYDROCHLORIDE BP	
87	NORTRIPTYLINE HYDROCHLORIDE EP	
88	NORTRIPTYLINE HYDROCHLORIDE IP	



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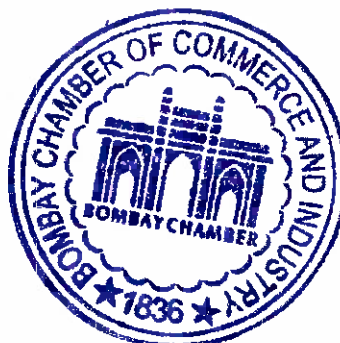
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- NEW-WHO-GMP/CERT/KD/85796/2019/11
/29756

Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Oct 2019

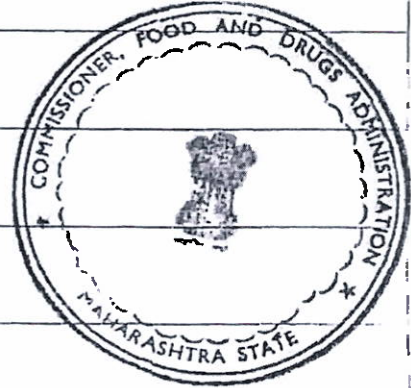
11 OCT 2019



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/KD/85796/2019/11 VALID UP TO : 10 Oct 2022 /29756
 Name of Manufacturing 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
89	NORTRIPTYLINE HYDROCHLORIDE JP	
90	NORTRIPTYLINE HYDROCHLORIDE USP	
91	OLOPATADINE HYDROCHLORIDE IP	
92	OLOPATADINE HYDROCHLORIDE USP	
93	OXAZEPAM BP	
94	OXAZEPAM EP	
95	OXAZEPAM IP	
96	OXAZEPAM USP	



... 8 9 10 11 12 13 14 15 16 17

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

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

Sr.No.	Name of the Product	Composition
97	PINDOLOL BP	
98	PINDOLOL EP	
99	PINDOLOL JP	
100	PINDOLOL USP	
101	PITOFENONE HYDROCHLORIDE	
102	PRAZEPAM BP	
103	PRAZEPAM EP	
104	PRAZEPAM JP	



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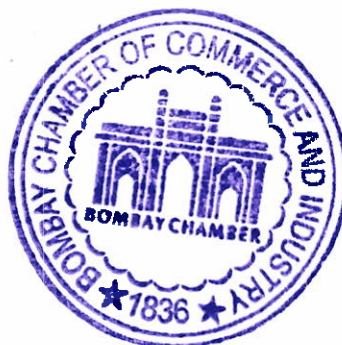
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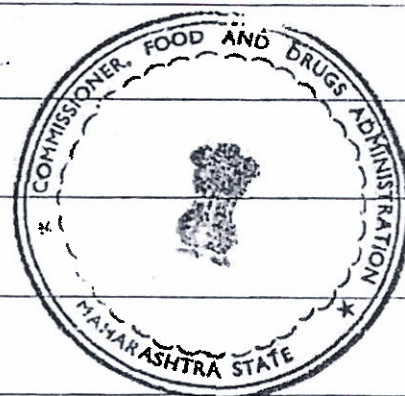
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MAHARASHTRA STATE, INDIA

Drug License No : KD1149 In Form 25, KD6
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Sr.No.	Name of the Product	Composition
105	PROPIVERINE HYDROCHLORIDE JP	
106	REBAMIPIDE IP	
107	RIVASTIGMINE HYDROGEN TARTRATE	
108	SODIUM OXYBATE (GAMMA HYDROXY BUTYRATE SODIUM)	
109	TEMAZEPAM BP	
110	TEMAZEPAM EP	
111	TEMAZEPAM USP	
112	TETRABENAZINE	



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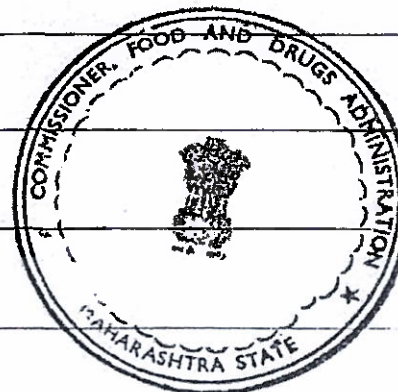
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Sr.No.	Name of the Product	Composition
113	TIMONIUM METHYL SULFATE	
114	TIMOLOL MALEATE BP	
115	TIMOLOL MALEATE EP	
116	TIMOLOL MALEATE IP	
117	TIMOLOL MALEATE JP	
118	TIMOLOL MALEATE USP	
119	TRANLYCYPROMINE SULPHATE BP	
120	TRANLYCYPROMINE SULPHATE USP	



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MAHARASHTRA STATE, INDIA

Drug License No : KD1149 In Form 25, KD6
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Sr.No.	Name of the Product	Composition
121	TRIAZOLAM USP	
122	ZALEPLON USP	
123	ZOLPIDEM TARTRATE BP	
124	ZOLPIDEM TARTRATE EP	
125	ZOLPIDEM TARTRATE IP	
126	ZOLPIDEM TARTRATE JP	
127	ZOLPIDEM TARTRATE USP	
128	ZOPICLONE BP	



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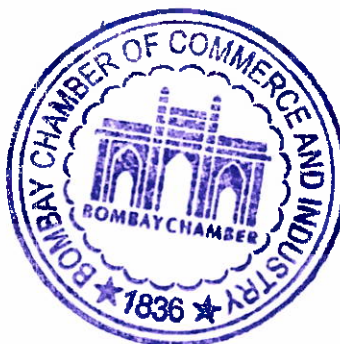
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MAHARASHTRA STATE, INDIA
Drug License No : KD1149 In Form 25, KD6
In Form 25F

Sr.No.	Name of the Product	Composition
129	ZOPICLONE EP	
130	ZOPICLONE IP	
131	ZUCLOPENTHIXOL ACETATE BP	

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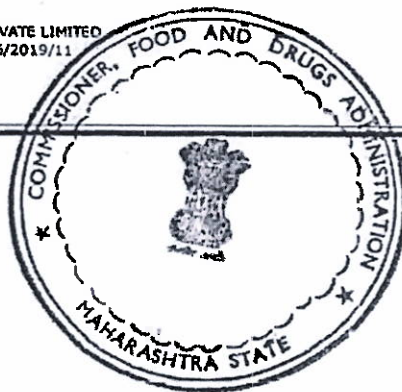
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