



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

Date : 30 AUG 2018

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/NKD/72512/2018/11/24746

On the basis of the inspection carried out on 28/05/2018 and 29/05/2018, 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 : SUN PHARMACEUTICAL INDUSTRIES LTD
Address : A-7/A-8, M.I.D.C, INDUSTRIAL AREA,
AHMEDNAGAR 414111 MAHARASHTRA
STATE, INDIA
2. Licence No. : NKD32 In Form 25,
NKD39 In Form 28

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	Cytotoxics	Synthesis, Purification, 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.

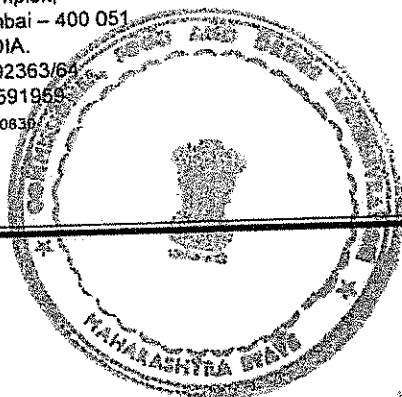
This certificate remains valid until 29 Aug 2021 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

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
1NUS7447251220180830

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: 30 Aug 2018



30 AUG 2018

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

VALID UP TO :29 Aug 2021

No. of certificate : NEW-WHO-GMP/CERT/NKD/72512
/2018/11/24746
Name of Manufacturing Firm : SUN PHARMACEUTICAL INDUSTRIES
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Drug License No : NKD32 In Form 25,
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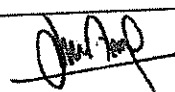
Sr.No.	Name of the Product	Composition
1	ABIRATERONE ACETATE IP	
2	ABIRATERONE ACETATE USP	
3	Abiraterone Acetate IH	
4	Acitretin BP	
5	Acitretin USP	
6	Adapalene BP	
7	Adapalene EP	
8	Amifostine USP	



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

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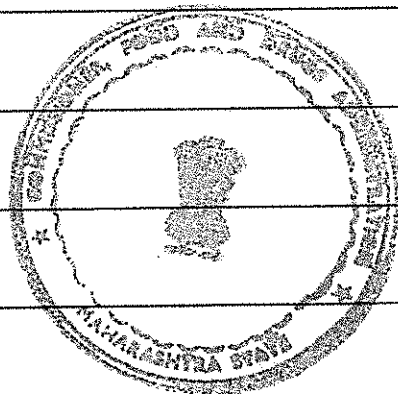
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Sr.No.	Name of the Product	Composition
9	Amisulpride BP	
10	Amisulpride EP	
11	Amisulpride IP	
12	Anastrozole EP	
13	Anastrozole IP	
14	Anastrozole USP	
15	Atorvastatin Calcium IP	
16	Atorvastatin Calcium USP	



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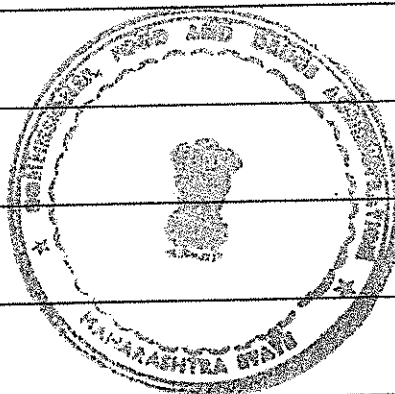
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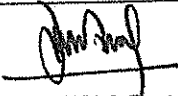
Sr.No.	Name of the Product	Composition
17	Atosiban Acetate IH	
18	Atosiban Acetate IP	
19	Azacitidine IH	
20	Azacitidine IP	
21	Bicalutamide IP	
22	Bicalutamide USP	
23	Bivalirudin IH	
24	Bortezomib IH	



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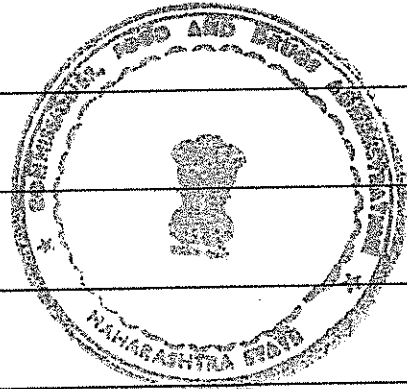
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Sr.No.	Name of the Product	Composition
25	Bupropion Hydrochloride USP	
26	Calcitonin (Salmon) BP	
27	Calcitonin (Salmon) EP	
28	Capecitabine IP	
29	Capecitabine USP	
30	Carboplatin BP	
31	Carboplatin EP	
32	Carboplatin IP	



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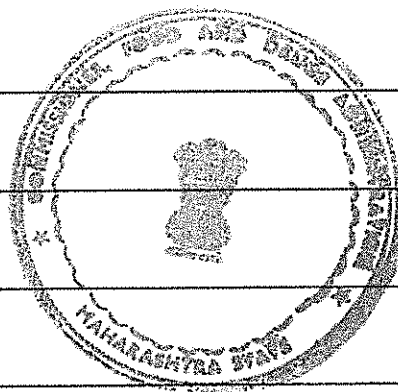
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Sr.No.	Name of the Product	Composition
33	Carboplatin USP	
34	Chlorothiazide USP	
35	Cisplatin BP	
36	Cisplatin EP	
37	Cisplatin IP	
38	Cisplatin USP	
39	Clonazepam BP	
40	Clonazepam EP	



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Sr.No.	Name of the Product	Composition
41	Clonazepam IP	
42	Clonazepam USP	
43	Clopidogrel Bisulfate USP	
44	Clopidogrel Bisulphate IP	
45	Dabigatran Etxilate Mesylate IH	
46	Decitabine IH	
47	Desloratadine IH	
48	Desmopressin Acetate BP	



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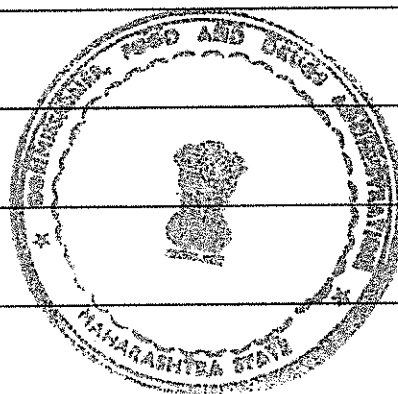
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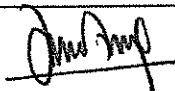
Sr.No.	Name of the Product	Composition
49	Desmopressin Acetate EP	
50	Desmopressin Acetate USP	
51	Disodium Pamidronate BP	
52	Disodium Pamidronate EP	
53	Disodium Pamidronate USP	
54	Divalproex Sodium USP	
55	Dobutamine Hydrochloride BP	
56	Dobutamine Hydrochloride EP	



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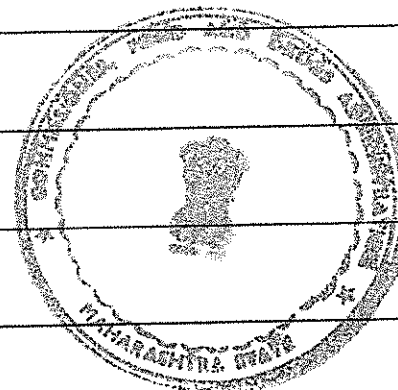
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Sr.No.	Name of the Product	Composition
57	Dobutamine Hydrochloride JP	
58	Dobutamine Hydrochloride USP	
59	Donepezil Hydrochloride IP	
60	Donepezil Hydrochloride USP	
61	Dothiepin Hydrochloride / Dosulepin Hydrochloride BP	
62	Dothiepin Hydrochloride / Dosulepin Hydrochloride EP	
63	Dothiepin Hydrochloride / Dosulepin Hydrochloride IP	
64	Eptifibatide IH	



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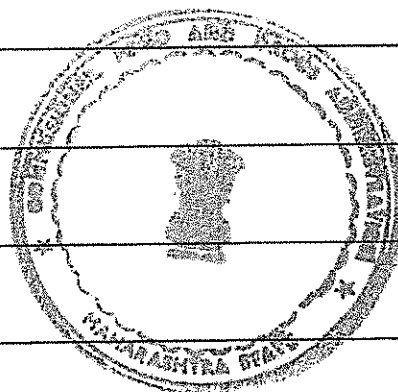
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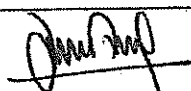
Sr.No.	Name of the Product	Composition
65	Erlotinib Hydrochloride IH	
66	Esomeprazole magnesium BP	
67	Esomeprazole magnesium EP	
68	Esomeprazole magnesium IP	
69	Esomeprazole magnesium USP	
70	Eszopiclone IH	
71	Eszopiclone USP	
72	Exenatide IH	



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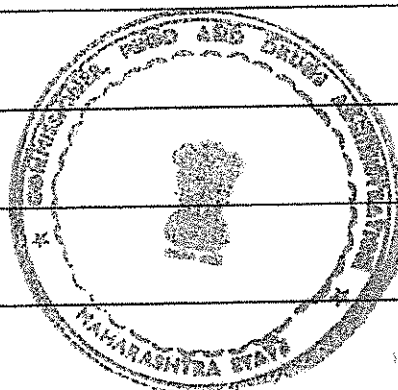
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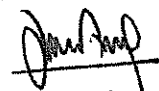
Sr.No.	Name of the Product	Composition
73	Febuxostat IH	
74	Finasteride BP	
75	Finasteride EP	
76	Finasteride USP	
77	Flurbiprofen BP	
78	Flurbiprofen EP	
79	Flurbiprofen IP	
80	Flurbiprofen JP	



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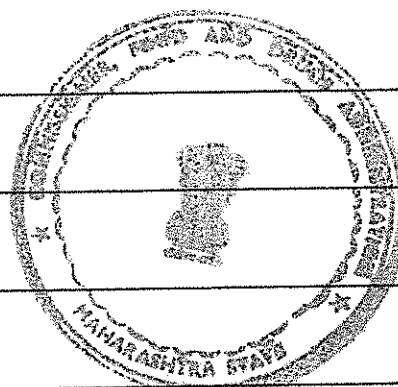
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Sr.No.	Name of the Product	Composition
81	Flurbiprofen Sodium BP	
82	Flurbiprofen Sodium IP	
83	Flurbiprofen Sodium USP	
84	Flurbiprofen USP	
85	Fluvoxamine Maleate BP	
86	Fluvoxamine Maleate IP	
87	Fluvoxamine Maleate USP	
88	Fulvestrant EP	



... 11 12 13 14 15 16 17 18 19 20 ...

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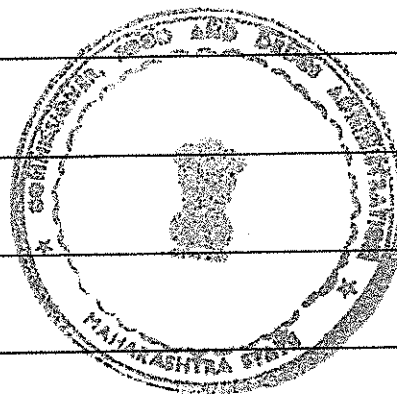
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Sr.No.	Name of the Product	Composition
89	Fulvestrant USP	
90	Gabapentin USP	
91	Ganirelix IH	
92	Gemcitabine Hydrochloride BP	
93	Gemcitabine Hydrochloride EP	
94	Gemcitabine Hydrochloride IP	
95	Gemcitabine Hydrochloride USP	
96	Ibandronic acid monosodium monohydrate IH	



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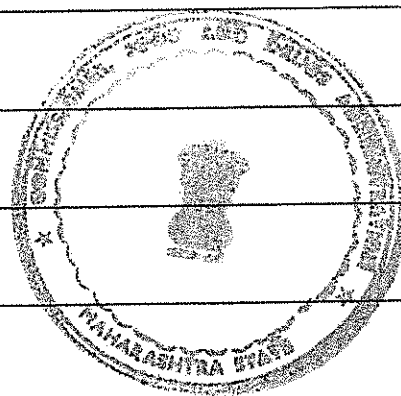
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97	Ibrutinib IH	
98	Imatinib Mesylate IP	
99	Irinotecan Hydrochloride trihydrate IP	
100	Isotretinoin BP	
101	Isotretinoin EP	
102	Isotretinoin USP	
103	Isradipine BP	
104	Isradipine USP	



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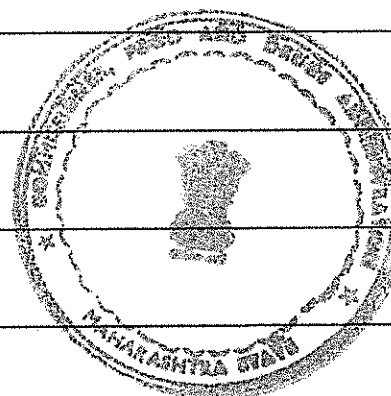
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Sr.No.	Name of the Product	Composition
105	Lamotrigine BP	
106	Lamotrigine EP	
107	Lamotrigine IP	
108	Lamotrigine USP	
109	Lansoprazole BP	
110	Lansoprazole EP	
111	Lansoprazole IP	
112	Lansoprazole USP	



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LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/NKD/72512 VALID UP TO :29 Aug 2021
/2018/11/24746
Name of Manufacturing Firm : SUN PHARMACEUTICAL INDUSTRIES
LTD
A-7/A-8, M.I.D.C, INDUSTRIAL AREA,
AHMEDNAGAR 414111 MAHARASHTRA STATE,
INDIA
Drug License No : NKD32 In Form 25,
NKD39 In Form 28

Sr.No.	Name of the Product	Composition
113	Lenalidomide IH	
114	Lercanidipine Hydrochloride IH	
115	Letrozole BP	
116	Letrozole EP	
117	Letrozole USP	
118	Leuprolide acetate BP	
119	Leuprolide acetate USP	
120	Linagliptin IH	

... 11 12 13 14 15 16 17 18 19 20 ...

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
1NUS7447251220180830

Name of the Authorised person : A. T. NIKHADE

Signature :

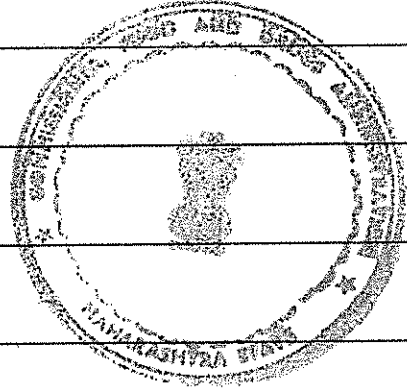
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Sr.No.	Name of the Product	Composition
121	Meloxicam BP	
122	Meloxicam EP	
123	Meloxicam USP	
124	Memantine Hydrochloride IH	
125	Memantine Hydrochloride USP	
126	Mesalamine / Mesalazine BP	
127	Mesalamine / Mesalazine EP	
128	Mesalamine / Mesalazine USP	



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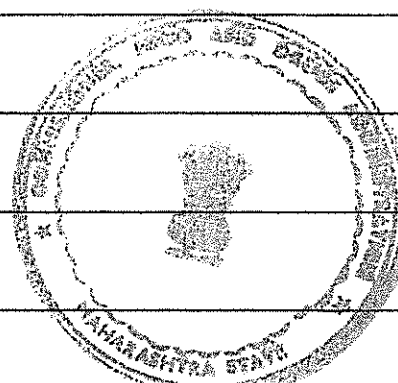
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Sr.No.	Name of the Product	Composition
129	Mesalazine IP	
130	Metformin Hydrochloride BP	
131	Metformin Hydrochloride EP	
132	Metformin Hydrochloride IP	
133	Metformin Hydrochloride USP	
134	Metoprolol Succinate BP	
135	Metoprolol Succinate EP	
136	Metoprolol Succinate USP	



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Sr.No.	Name of the Product	Composition
137	Metoprolol Tartrate BP	
138	Metoprolol Tartrate EP	
139	Metoprolol Tartrate IP	
140	Metoprolol Tartrate USP	
141	Mitoxantrone Hydrochloride BP	
142	Mitoxantrone Hydrochloride EP	
143	Mitoxantrone Hydrochloride USP	
144	Naratriptan Hydrochloride USP	



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Sr.No.	Name of the Product	Composition
145	Octreotide Acetate IH	
146	Octreotide acetate USP	
147	Olanzapine IP	
148	Olanzapine USP	
149	Olanzapine EP	
150	Olopatadine Hydrochloride USP	
151	Omeprazole EP	
152	Omeprazole IP	

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Sr.No.	Name of the Product	Composition
153	Omeprazole Magnesium USP	
154	Omeprazole USP	
155	Oxaliplatin BP	
156	Oxaliplatin EP	
157	Oxaliplatin USP	
158	Oxpentifylline / Pentoxifylline BP	
159	Oxpentifylline / Pentoxifylline EP	
160	Oxpentifylline / Pentoxifylline USP	

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Sr.No.	Name of the Product	Composition
161	Paliperidone IH	
162	Pantoprazole Sodium BP	
163	Pantoprazole Sodium IP	
164	Pantoprazole Sodium USP	
165	Pemetrexed Disodium Heptahydrate EP	
166	Pemetrexed Disodium Heptahydrate IH	
167	Phentermine Hydrochloride USP	
168	Piroxicam Betacyclodextrin IH	

... 17 18 19 20 21 22 23 24 25 26

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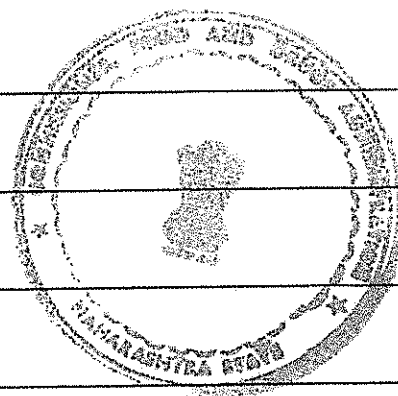
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Sr.No.	Name of the Product	Composition
169	Pregabalin EP	
170	Pregabalin IH	
171	Pregabalin IP	
172	Quetiapine Fumarate IH	
173	Quetiapine Fumarate IP	
174	Risedronate Sodium USP	
175	Rivastigmine Tartrate USP	
176	Rivastigmine USP	



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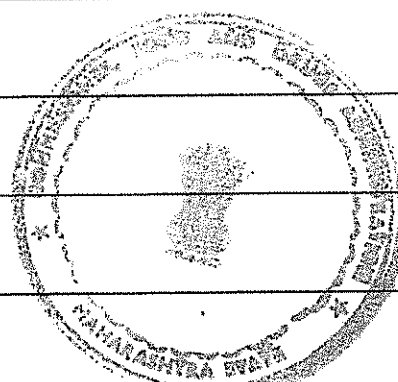
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Sr.No.	Name of the Product	Composition
177	Saxagliptin IH	
178	Sodium Valproate BP	
179	Sodium Valproate EP	
180	Sodium Valproate IP	
181	Sunitinib malate IH	
182	Tadalafil EP	
183	Tadalafil USP	
184	Tazarotene IH	



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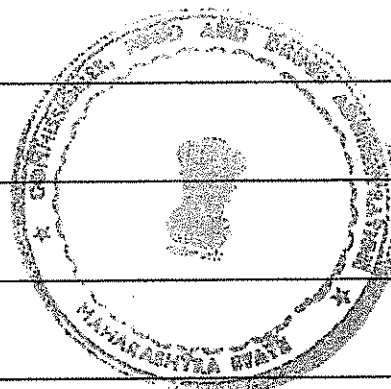
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Drug License No : NKD32 In Form 25,
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Sr.No.	Name of the Product	Composition
185	Temozolomide IP	
186	Temozolomide USP	
187	Temsirolimus IH	
188	Teriparatide IH	
189	Terlipressin Acetate IH	
190	Tetrabenazine IH	
191	Tramadol Hydrochloride EP	
192	Tramadol Hydrochloride IP	



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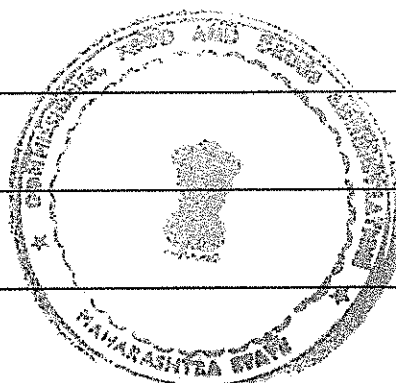
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Drug License No : NKD32 In Form 25,
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Sr.No.	Name of the Product	Composition
193	Tramadol Hydrochloride USP	
194	Valproic Acid BP	
195	Valproic Acid EP	
196	Valproic Acid USP	
197	Venlafaxine Hydrochloride BP	
198	Venlafaxine Hydrochloride EP	
199	Venlafaxine Hydrochloride USP	
200	Ziprasidone Hydrochloride IH	



... 17 18 19 20 21 22 23 24 25 26

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Sr.No.	Name of the Product	Composition
201	Zoledronic Acid IP	
202	IMATINIB MESYLATE (In House)	
203	Olopatadine Hydrochloride Olopatadine Hydrochloride	
204	Prasugrel Hydrochloride Prasugrel Hydrochloride	

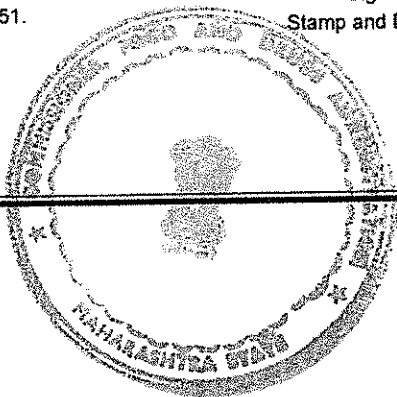
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