No. HFW-NZ(Drugs)2026 - 4012
Health & Family Welfare Deparment H.P.
Drugs Control Administration HP,
O/o CMO's Office Complex, Dharmshala-176215, Kangra, H.P.

Date: 06/01/26

FREE SALE CERTIFICATE

Certified that ***M/s, Kwality Pharmaceuticals Limited, Situated at, 1-A Industrial Area, Raja Ka Bagh, Tehsil Nurpur Himachal Pradesh, INDIA*** is licensed to manufacture drugs for sale or for distribution, under license No. **Form 25: *NNZ/08/40 and Form 28: BNZ/08/41*** issued by this Department on ***17.11.2025*** *and is renewed up- to* ***27.12.2030,*** under the provisions of the Drugs and Cosmetics Act, 1940 and rules 1945 made there under.

1. The said licensee is permitted to manufacture for sale or distribution drugs freely, in the domestic market subject to the provision of the Drugs and Cosmetics Act, 1940 and rules 1945, made there under.

2. The said licensee is permitted to manufacture for sale or distribution drugs freely for export purpose, the drug as detailed below, to the various countries, subject to the rules and regulation of the importing countries, as per Annexure –"A" duly signed.

3. This certificate is issued to the firm, on their request, for registering the aforesaid product in the overseas countries.

06/01/26
Asstt. Drugs Controller,
Cum- Drug Licensing Authority,
Distt. Kangra at Dharmshala H.P. INDIA

No. HFW-NZ (Drugs) 2026-4012, Dated: Dharmshala, the 06/01/26

Asstt. Drugs Controller Cum
Drug Licensing Authority
Distt. Kangra at Dharamshala (H.P)

Issued to:

M/s, Kwality Pharmaceuticals Limited,
1-A Industrial Area, Raja Ka Bagh,
Tehsil Nurpur Himachal Pradesh, INDIA

Digitally signed by Dicusar Vladimir
Date: 2026.07.22 10:04:58 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Free Sale Certificate
Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
01.	**Carboplatin Injection BP 150mg /15ml**	Each ml contains : Carboplatin BP 10 mg Water for Injection BP q.s.
02.	**Carboplatin Injection BP 450mg /45ml**	Each ml contains : Carboplatin BP 10 mg Water for Injection BP q.s.
03.	**Cisplatin Injection BP 10mg /10ml**	Each ml contains : Cisplatin BP 1 mg Water for Injection BP q.s.
04.	**Cisplatin Injection BP 50mg /50ml**	Each ml contains : Cisplatin BP 1 mg Water for Injection BP q.s.
05.	**Cytarabine Injection BP 100mg /ml**	Each ml contains : Cytarabine BP 100 mg Water for Injection BP q.s.
06.	**Oxaliplatin Injection USP 50mg /25ml**	Each ml contains : Oxaliplatin BP 2 mg Water for Injection BP q.s.
07.	**Oxaliplatin Injection USP 100mg /50ml**	Each ml contains : Oxaliplatin BP 2 mg Water for Injection BP q.s.
08.	**Calcium Folinate Injection BP 50mg /5ml**	Each ml contains : Calcium Folinate BP Eq. to Folinic Acid 10 mg Water for Injection BP q.s.
09.	**Leucovorin Calcium Injection USP 50mg /5ml**	Each 5ml contains : Leucovorin Calcium USP Eq. to Leucovorin 50 mg Water for Injection USP q.s.
10.	**Etoposide Injection USP 100mg /5ml**	Each ml contains : Etoposide USP 20 mg Benzyl Alcohol USP 30 mg (As Preservative) Ethyl Alcohol USP 30. 5% v/v Sterile non aqueous vehicle q.s.
11.	**Vinblastine Injection BP 10mg /10ml**	Each ml contains : Vinblastine Sulfate BP 1 mg Sodium Chloride BP 9 mg Benzyl Alcohol BP 0. 9% v/v Water for Injection BP q.s.

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
12.	**Doxorubicin Hydrochloride Liposome Injection (As Pegylated Liposome) 20mg/ 10ml**	Each ml contains : Doxorubicin Hydrochloride BP 2 mg (As Pegylated Liposome) Water for Injection BP q.s.
13.	**Docetaxel Injection USP 20mg/ 0.5ml** **Solvent For Docetaxel Injection USP 20mg/ 0.5ml**	Each single dose vial contains : Docetaxel Trihydrate USP Eq. to anhydrous Docetaxel 20 mg Polysorbate 80 USP q.s. to 0.5ml Each vial contains : Alcohol (95% v/v) USP 13% w/v (Absolute Alcohol content 15.25% v/v) Water for Injection USP q.s. to 1.5 ml
14.	**Docetaxel Injection USP 80mg/ 2ml** **Solvent For Docetaxel Injection USP 80mg/ 2ml**	Each single dose vial contains : Docetaxel Trihydrate USP Eq. to anhydrous Docetaxel 80 mg Polysorbate 80 USP q.s. to 2ml Each vial contains : Alcohol (95% v/v) USP 13% w/v (Absolute Alcohol content 15.25% v/v) Water for Injection USP q.s. to 6 ml
15.	**Docetaxel Injection USP 120mg/ 3ml** **Solvent For Docetaxel Injection USP 120mg/ 3ml**	Each single dose vial contains : Docetaxel Trihydrate USP Eq. to anhydrous Docetaxel 120 mg Polysorbate 80 USP q.s. to 3ml Each vial contains : Alcohol (95% v/v) USP 13% w/v (Absolute Alcohol content 15.25% v/v) Water for Injection USP q.s. to 9 ml
16.	**Irinotecan Hydrochloride Injection USP 40mg /2ml**	Each ml contains : Irinotecan Hydrochloride USP 20 mg Water for Injection USP q.s.
17.	**Irinotecan Hydrochloride Injection USP 100mg /5ml**	Each ml contains : Irinotecan Hydrochloride USP 20 mg Water for Injection USP q.s.
18.	**Vinorelbine Injection USP 10mg / ml**	Each ml contains : Vinorelbine Tartrate USP Eq. to Vinorelbine 10 mg Water for Injection USP q.s.

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
19.	**Paclitaxel Injection USP 30mg / 5ml**	Each ml contains : Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP NF 527 mg Dehydrated Alcohol USP NF 49.7% v/v
20.	**Paclitaxel Injection USP 100mg / 16.7ml**	Each ml contains : Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP NF 527 mg Dehydrated Alcohol USP NF 49.7% v/v
21.	**Paclitaxel Injection USP 260mg / 43.4ml**	Each ml contains : Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP NF 527 mg Dehydrated Alcohol USP NF 49.7% v/v
22.	**Paclitaxel Injection USP 300mg / 50ml**	Each ml contains : Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP NF 527 mg Dehydrated Alcohol USP NF 49.7% v/v
23.	**Epirubicin Injection BP 10mg / 5ml**	Each ml contains : Epirubicin Hydrochloride BP 2 mg Water for Injection BP q.s.
24.	**Epirubicin Injection BP 50mg / 25ml**	Each ml contains : Epirubicin Hydrochloride BP 2 mg Water for Injection BP q.s.
25.	**Mitoxantrone Injection USP 20mg / 10 ml**	Each ml contains : Mitoxantrone Hydrochloride USP Eq. to Mitoxantrone 2 mg Water for Injection USP q.s.
26.	**Fulvestrant Injection 250mg / 5ml**	Each ml contains : Fulvestrant 50 mg Water for Injection BP q.s.
27.	**Methotrexate Injection BP 50mg / 2 ml**	Each ml contains : Methotrexate BP 25 mg Sodium Hydroxide BP q.s. Water for Injection BP q.s.
28.	**Doxorubicin Hydrochloride Pegylated Liposomal Injection 50mg/ 25ml**	Each ml contains : Doxorubicin Hydrochloride BP 2 mg (As Pegylated Liposomal) Water for Injection BP q.s.
29.	**Pegaspargase Injection 3750 IU/ 5ml**	Each 5ml contains : Pegaspargase 3750 IU (Pegylated L-Asparaginase)

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
30.	**Cytarabine Injection BP 100mg / 5ml**	Each ml contains : Cytarabine BP 20 mg Water for Injection BP q.s.
31.	**Vincristine Sulfate Injection USP 1mg / ml**	Each ml contains : Vincristine Sulfate USP 1 mg Water for Injection USP q.s.
32.	**Vincristine Sulfate Injection USP 2mg / 2ml**	Each ml contains : Vincristine Sulfate USP 1 mg Water for Injection USP q.s.
33.	**Vinorelbine Injection USP 50mg / 5ml**	Each ml contains : Vinorelbine Tartrate USP Eq. to Vinorelbine 10 mg Water for Injection USP q.s.
34.	**Topotecan Injection Concentrate 4mg / 4ml**	Each ml contains : Topotecan Hydrochloride Eq. to Topotecan 1 mg Water for Injection BP q.s.
35.	**Cladribine Injection USP 10mg / 10ml**	Each ml contains : Cladribine USP 1 mg Sodium Chloride BP 9 mg Water for Injection USP q.s.
36.	**Fluorouracil Injection BP 250mg / 5ml**	Each ml contains : Fluorouracil BP 50 mg Sodium Hydroxide BP 10 mg Water for Injection BP q.s.
37.	**Fluorouracil Injection BP 500mg / 10ml**	Each ml contains : Fluorouracil BP 50 mg Sodium Hydroxide BP 10 mg Water for Injection BP q.s.
38.	**Docetaxel Injection USP 40mg/ ml** **Solvent For Docetaxel Injection USP 40mg/ ml**	Each single dose vial contains : Docetaxel Trihydrate USP Eq. to anhydrous Docetaxel 40 mg Polysorbate 80 USP q.s. to 1ml Each vial contains : Alcohol (95% v/v) USP 13% w/v (Absolute Alcohol content 15.25% v/v) Water for Injection USP q.s. to 3 ml
39.	**Goserelin Acetate Injection 3.6 mg / ml**	Each ml contains : Goserelin Acetate Eq. to Goserelin 3.6 mg Water for Injection BP q.s.

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
40.	**Carboplatin Injection BP 50mg / 5ml**	Each ml contains : Carboplatin BP 10 mg Water for Injection BP q.s.
41.	**Mesna Injection 200mg / 2ml**	Each ml contains : Mesna BP 100 mg Water for Injection BP q.s.
42.	**Vinblastine Injection BP 5mg / 5ml**	Each ml contains : Vinblastine Sulfate BP 1 mg Sodium Chloride BP 9 mg Benzyl Alcohol BP 0. 9% v/v Water for Injection BP q.s.
43.	**Vinblastine Injection BP 10mg / 10ml**	Each ml contains : Vinblastine Sulfate BP 1 mg Sodium Chloride BP 9 mg Benzyl Alcohol BP 0. 9% v/v Water for Injection BP q.s.
44.	**Docetaxel Injection USP 20mg/ ml**	Each ml contains : Docetaxel Anhydrous USP 20 mg Citric Acid Anhydrous USP 4 mg Polysorbate 80 USP 520 mg Dehydrated Alcohol USP 395 mg
45.	**Docetaxel Injection USP 40mg/ 2ml**	Each ml contains : Docetaxel Anhydrous USP 20 mg Citric Acid Anhydrous USP 4 mg Polysorbate 80 USP 520 mg Dehydrated Alcohol USP 395 mg
46.	**Docetaxel Injection USP 80mg/ 4ml**	Each ml contains : Docetaxel Anhydrous USP 20 mg Citric Acid Anhydrous USP 4 mg Polysorbate 80 USP 520 mg Dehydrated Alcohol USP 395 mg
47.	**Docetaxel Injection USP 120mg/ 6ml**	Each ml contains : Docetaxel Anhydrous USP 20 mg Citric Acid Anhydrous USP 4 mg Polysorbate 80 USP 520 mg Dehydrated Alcohol USP 395 mg
48.	**Oxaliplatin Injection USP 5mg / 5ml**	Each ml contains : Oxaliplatin USP 5 mg Water for Injection USP q.s.

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
49.	**Oxaliplatin Injection USP 50mg / 10ml**	Each ml contains : Oxaliplatin USP 5 mg Water for Injection USP q.s.
50.	**Oxaliplatin Injection USP 100mg / 20ml**	Each ml contains : Oxaliplatin USP 5 mg Water for Injection USP q.s.
51.	**Oxaliplatin Injection USP 200mg / 40ml**	Each ml contains : Oxaliplatin USP 5 mg Water for Injection USP q.s.
52.	**Cisplatin Injection BP 25mg / 25ml**	Each ml contains : Cisplatin BP 1 mg Water for Injection BP q.s.
53.	**Leucovorin Calcium Injection USP 10mg /ml**	Each ml contains : Leucovorin Calcium USP Eq. to Leucovorin 10 mg Water for Injection USP q.s.
54.	**Docetaxel Injection 20mg/ 0.5ml** **Solvent For Docetaxel Injection 20mg/ 0.5ml**	Each single dose vial contains : Docetaxel Trihydrate BP Eq. to anhydrous Docetaxel 20 mg Polysorbate 80 BP q.s. to 0.5ml Each vial contains : Alcohol (95% v/v) BP 13% w/v (Absolute Alcohol content 15.25% v/v) Water for Injection BP q.s. to 1.5 ml
55.	**Docetaxel Injection 80mg/ 2ml** **Solvent For Docetaxel Injection 80mg/ 2ml**	Each single dose vial contains : Docetaxel Trihydrate BP Eq. to anhydrous Docetaxel 80 mg Polysorbate 80 BP q.s. to 2ml Each vial contains : Alcohol (95% v/v) BP 13% w/v (Absolute Alcohol content 15.25% v/v) Water for Injection BP q.s. to 6 ml
56.	**Docetaxel Injection 120mg/ 3ml** **Solvent For Docetaxel Injection 120mg/ 3ml**	Each single dose vial contains : Docetaxel Trihydrate BP Eq. to anhydrous Docetaxel 120 mg Polysorbate 80 BP q.s. to 3ml Each vial contains : Alcohol (95% v/v) BP 13% w/v (Absolute Alcohol content 15.25% v/v) Water for Injection BP q.s. to 9 ml

06/01/26

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
57.	**Carboplatin Injection BP**	Each ml contains : Carboplatin BP 10 mg Water for Injection BP q.s.
58.	**Oxaliplatin Injection USP 50mg /25ml**	Each ml contains : Oxaliplatin USP 2 mg Water for Injection USP q.s.
59.	**Oxaliplatin Injection USP 100mg /50ml**	Each ml contains : Oxaliplatin USP 2 mg Water for Injection USP q.s.
60.	**Cytarabine Injection BP**	Each ml contains : Cytarabine BP 20 mg Water for Injection BP q.s.
61.	**Oxaliplatin For Injection**	Each ml contains : Oxaliplatin BP 2 mg Water for Injection BP q.s.
62.	**Methotrexate Injection BP 1000 mg / 10ml**	Each ml contains : Methotrexate BP 100 mg Water for Injection BP q.s.
63.	**Bevacizumab Injection 100mg/ 4ml**	Each ml contains : Bevacizumab 25 mg Water for Injection BP q.s.
64.	**Bevacizumab Injection 400mg/ 16ml**	Each ml contains : Bevacizumab 25 mg Water for Injection BP q.s.
65.	**Fulvestrant Injection 250mg / 5ml**	Each ml contains : Fulvestrant BP 50 mg Ethanol (96 per cent) BP 10% w/v
66.	**Goserelin Acetate Injection**	Each ml contains : Goserelin Acetate USP Eq. to Goserelin 10.8 mg Water for Injection USP q.s.
67.	**Methotrexate Injection BP 50 mg / 5ml**	Each ml contains : Methotrexate BP 10 mg Water for Injection BP q.s.
68.	**Paclitaxel Injection USP 150mg / 25 ml**	Each ml contains : Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP NF 527 mg Dehydrated Alcohol USP NF 49.7% v/v

06/01/26

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
69.	**Mesna Injection 400mg / 4ml**	Each ml contains : Mesna BP 100 mg Water for Injection BP q.s.
70.	**Busulphan Injection 60mg / 10ml**	Each ml contains : Busulphan USP 6 mg N, N-Dimethyl Acetamide BP 0.33ml Polyethylene Glycol-400 USP NF 0.67ml
71.	**Doxorubicin Hydrochloride Injection BP 50mg/25ml**	Each ml contains: Doxorubicin Hydrochloride BP 2 mg Water for Injection BP q.s.
72.	**Daunorubicin Liposomal Injection 50mg/ vial 2mg/ml (50mg/25ml)**	Each ml contains : Daunorubicin Citrate Eq. to Daunorubicin 2 mg Water for Injection BP q.s.
73.	**Zoledronic Acid Injection 5mg/100ml**	Each ml contains: Zoledronic acid monohydrate Eq. to Zoledronic acid anhydrous 0.05 mg Water for Injection USP q.s.
74.	**Arsenic Trioxide Injection 1mg/ml**	Each ml contains : Arsenic Trioxide 1 mg Water for Injection USP q.s.
75.	**Methotrexate Injection BP 5gm/50ml**	Each ml contains : Methotrexate BP 100 mg Water for Injection BP q.s.
76.	**Octreotide Acetae Injection 100mcg/ml**	Each ml contains : Octreotide Acetate USP Eq. to Octreotide 100 mcg Water for Injection USP q.s.
77.	**Octreotide Acetae Injection 50mcg/ml**	Each ml contains : Octreotide Acetate USP Eq. to Octreotide 50 mcg Water for Injection USP q.s.
78.	**Doxorubicin Hydrochloride Liposome Injection 20mg/10ml (2mg/ml)**	Each ml contains : Doxorubicin Hydrochloride BP 20 mg (As Pegylated Liposome) Water for Injection BP q.s.
79.	**Octreotide Acetae Injection 200mcg/ml**	Each ml contains : Octreotide Acetate USP Eq. to Octreotide 200 mcg Water for Injection USP q.s.

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
80.	**Cisplatin Injection BP 100mg/100ml**	Each ml contains : Cisplatin BP 1 mg Water for Injection BP q.s.
81.	**Clofarabine Injection 20mg/20ml**	Each ml contains : Clofarabine 1 mg Water for Injection USP q.s.
82.	**Vinorelbine Injection USP 20mg/2ml**	Each ml contains : Vinorelbine Tartrate USP Eq. to Vinorelbine 10 mg Water for injection USP q.s.
83.	**Vinorelbine Injection USP 30mg/3ml**	Each ml contains : Vinorelbine Tartrate USP Eq. to Vinorelbine 10 mg Water for injection USP q.s.
84.	**Vinblastine Sulfate Solution For Injection BP 10mg / 10ml**	Each ml contains : Vinblastine Sulfate BP 1 mg Sodium Chloride BP 9 mg Benzyl Alcohol BP 0.9% v/v Water for Injection BP q.s.
85.	**Doxorubicin Hydrochloride Injection USP 50mg/25ml**	Each ml contains: Doxorubicin Hydrochloride USP 2 mg Water for injection USP q.s.
86.	**Cisplatin Injection USP 50mg/50ml**	Each ml contains : Cisplatin USP 1 mg Water for injection USP q.s.
87.	**Mitoxantrone Injection USP 2mg / ml (10mg/5ml)**	Each ml contains : Mitoxantrone Hydrochloride USP Eq. to Mitoxantrone 2 mg Water for injection USP q.s.
88.	**Calcium Folinate Injection BP 10mg/ml (300mg/30ml)**	Each ml contains: Calcium Folinate BP Eq. to Folinic Acid 10 mg Water for Injection BP q.s.
89.	**Methotrexate Injection USP 50mg/2ml**	Each ml contains : Methotrexate USP 25 mg Water for injection USP q.s.

06/01/26

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
90.	**Pemetrexed For Injection USP 500mg/vial**	Each vial contains: Pemetrexed Disodium USP Eq. to Pemetrexed 500 mg Excipients q.s.
91.	**Plerixafor Injection 20mg/ml (24mg/1.2ml)**	Each ml contains: Plerixafor 20 mg Water for injection USP q.s.
92.	**Cyclophosphamide For Injection BP 100mg/vial (As Lyophilized)**	Each vial contains : Cyclophosphamide BP Eq. to anhydrous Cyclophosphamide 100 mg Excipients q.s.

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Free Sale Certificate
Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
93.	**Capecitabine Tablets USP 500 mg**	Each film coated tablet contains : Capecitabine USP 500 mg Excipients q.s. Colour : Approved colours used
94.	**Gefitinib Tablets 250 mg**	Each film coated tablet contains : Gefitinib 250 mg Excipients q.s. Colour : Approved colours used
95.	**Imatinib Tablets 400 mg**	Each film coated tablet contains : Imatinib Mesylate BP Eq. to Imatinib 400 mg Excipients q.s. Colour : Approved colours used
96.	**Methotrexate Tablets BP 2.5 mg**	Each uncoated tablet contains : Methotrexate BP 2.5 mg Excipients q.s.
97.	**Letrozole Tablets USP 2.5 mg**	Each film coated tablet contains : Letrozole USP 2.5 mg Excipients q.s. Colour : Approved colours used
98.	**Dasatinib Tablets 50mg**	Each film coated tablet contains : Dasatinib 50mg Excipients q.s. Colour : Approved colours used
99.	**Dasatinib Tablets 70mg**	Each film coated tablet contains : Dasatinib 70mg Excipients q.s. Colour : Approved colours used
100.	**Dasatinib Tablets 100mg**	Each film coated tablet contains : Dasatinib 100mg Excipients q.s. Colour : Approved colours used
101.	**Mercaptopurine Tablets BP 50mg**	Each uncoated tablet contains : Mercaptopurine BP 50 mg Excipients q.s.
102.	**Tamoxifen Tablets BP 10mg**	Each uncoated tablet contains : Tamoxifen Citrate BP Eq. to Tamoxifen 10mg Excipients q.s.

06/01/26

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Annexure –A

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
103.	**Tamoxifen Tablets BP 20mg**	Each uncoated tablet contains : Tamoxifen Citrate BP Eq. to Tamoxifen 20mg Excipients q.s.
104.	**Tamoxifen Tablets BP 40mg**	Each uncoated tablet contains : Tamoxifen Citrate BP Eq. to Tamoxifen 40mg Excipients q.s.
105.	**Capecitabine Tablets USP 150mg**	Each film coated tablet contains : Capecitabine USP 150 mg Excipients q.s. Colour : Approved colours used
106.	**Melphalan Tablets BP 2mg**	Each film coated tablet contains : Melphalan BP 2mg Excipients q.s. Colour : Approved colours used
107.	**Melphalan Tablets BP 4mg**	Each film coated tablet contains : Melphalan BP 4mg Excipients q.s. Colour : Approved colours used
108.	**Flutamide Tablets 250 mg**	Each uncoated tablet contains : Flutamide USP 250mg Excipients q.s.
109.	**Lapatinib Tablets 250 mg**	Each film coated tablet contains : Lapatinib Ditosylate Eq. to Lapatinib 250mg Excipients q.s. Colour : Approved colours used
110.	**Chlorambucil Tablets BP 2mg**	Each film coated tablet contains : Chlorambucil BP 2mg Excipients q.s. Colour : Approved colours used
111.	**Chlorambucil Tablets BP 5mg**	Each film coated tablet contains : Chlorambucil BP 5mg Excipients q.s. Colour : Approved colours used
112.	**Sorafenib Tablets 200mg**	Each film coated tablet contains : Sorafenib Tosylate Eq. to Sorafenib 200mg Excipients q.s. Colour : Approved colours used

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No. HFW-NZ (Drugs) 2026-4012, Dated: Dharmshala, the 06/01/26

Issued to:

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
113.	**Imatinib Tablets 100 mg**	Each film coated tablet contains : Imatinib Mesylate BP Eq. to Imatinib 100mg Excipients q.s. Colour : Approved colours used
114.	**Cyclophosphamide Tablets USP 50mg**	Each film coated tablet contains : Cyclophosphamide USP Eq. to anhydrous Cyclophosphamide 50mg Excipients q.s. Colour : Approved colours used
115.	**Erlotinib Tablets 100 mg**	Each film coated tablet contains : Erlotinib Hydrochloride Eq. to Erlotinib 100mg Excipients q.s. Colour : Approved colours used
116.	**Erlotinib Tablets 150 mg**	Each film coated tablet contains : Erlotinib Hydrochloride Eq. to Erlotinib 150mg Excipients q.s. Colour : Approved colours used
117.	**Afatinib Tablets 20mg**	Each film coated tablet contains : Afatinib dimaleate 29.56mg Eq. to Afatinib 20mg Excipients q.s. Colour : Approved colours used
118.	**Afatinib Tablets 30mg**	Each film coated tablet contains : Afatinib dimaleate 44.34mg Eq. to Afatinib 30mg Excipients q.s. Colour : Approved colours used
119.	**Afatinib Tablets 40mg**	Each film coated tablet contains : Afatinib dimaleate 59.12mg Eq. to Afatinib 40mg Excipients q.s. Colour : Approved colours used
120.	**Afatinib Tablets 50mg**	Each film coated tablet contains : Afatinib dimaleate 73.9mg Eq. to Afatinib 50mg Excipients q.s. Colour : Approved colours used

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
121.	**Anastrozole Tablets USP 1mg**	Each film coated tablet contains : Anastrozole USP 1mg Excipients q.s. Colour : Approved colours used
122.	**Thioguanine Tablest USP 40mg**	Each uncoated tablet contains : Thioguanine USP 40mg Excipients q.s.
123.	**Cyclophosphamide Tablets BP 50mg**	Each sugar coated tablet contains : Cyclophosphamide BP Eq. to anhydrous Cyclophosphamide 50mg Excipients q.s. Colour : Approved colours used
124.	**Letrozole Tablets USP 2.5 mg**	Each uncoated tablet contains : Letrozole USP 2.5mg Excipients q.s.
125.	**Bedaquiline Tablets 100 mg**	Each uncoated tablet contains : Bedaquiline Fumarate Eq. to Bedaquiline 100mg Excipients q.s.
126.	**Pazopanib Tablets 200mg**	Each film coated tablet contains : Pazopanib Hydrochloride 216.7mg Eq. to Pazopanib 200mg Excipients q.s. Colour : Approved colours used
127.	**Pazopanib Tablets 400mg**	Each film coated tablet contains : Pazopanib Hydrochloride 433.4mg Eq. to Pazopanib 400mg Excipients q.s. Colour : Approved colours used
128.	**Dasatinib Tablets 20mg**	Each film coated tablet contains : Dasatinib 20 mg Excipients q.s. Colour : Approved colours used
129.	**Fludarabine Phosphate Tablets 10mg**	Each film coated tablet contains: Fludarabine Phosphate USP 10 mg Excipients q.s. Colour : Approved colours used
130.	**Azathioprine Tablets USP 50mg**	Each film coated tablet contains: Azathioprine USP 50 mg Excipients q.s. Colour : Approved colours used

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
131.	**Chlorambucil Tablets USP 2mg**	Each film coated tablet contains: Chlorambucil USP 2 mg Excipients q.s. Colour : Approved colours used
132.	**Abiraterone Acetate Tablets USP 250 mg**	Each uncoated tablet contains : Abiraterone Acetate USP 250 mg Excipients q.s.
133.	**Methotrexate Tablets BP 10 mg**	Each uncoated tablet contains : Methotrexate BP 10 mg Excipients q.s.
134.	**Exemestane Tablets 25mg**	Each film coated tablet contains : Exemestane 25 mg Excipients q.s. Colour : Approved colours used
135.	**Leflunomide Tablets USP 20mg**	Each film coated tablet contains : Leflunomide USP 20 mg Excipients q.s. Colour : Approved colours used
136.	**Abiraterone Acetate Tablets USP 250 mg**	Each film caoted tablet contains : Abiraterone Acetate USP 250 mg Excipients q.s. Colour : Approved colours used
137.	**Enzalutamide Tablets 40 mg**	Each film coated tablet contains : Enzalutamide 40 mg Excipients q.s. Colour : Approved colours used
138.	**Enzalutamide Tablets 80 mg**	Each film coated tablet contains : Enzalutamide 80 mg Excipients q.s. Colour : Approved colours used
139.	**Regorafenib Tablets 40mg**	Each film coated tablet contains : Regorafenib 40 mg Excipients q.s. Colour : Approved colours used
140.	**Everolimus Tablets 5 mg**	Each uncoated tablet contains : Everolimus 5 mg Excipients q.s.
141.	**Everolimus Tablets 10 mg**	Each uncoated tablet contains : Everolimus 10 mg Excipients q.s.

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
142.	**Tamoxifen Tablets BP 20mg**	Each uncoated tablet contains : Tamoxifen Citrate BP Eq. to Tamoxifen 20 mg Excipients q.s.
143.	**Calcium Folinate Tablets BP 15mg**	Each uncoated tablet contains : Calcium Folinate BP Eq. to Folinate Acid 15 mg Excipients q.s.
144.	**Sunitinib Maleate Tablets 50mg**	Each film coated tablets contains: Sunitnib Maleate Eq. to Sunitinib 50 mg Excipients q.s. Colour : Approved colours used
145.	**Everolimus Tablets 10 mg**	Each film coated tablets contains: Everolimus 10 mg Excipients q.s. Colour : Approved colours used
146.	**Everolimus Tablets 5 mg**	Each film coated tablets contains: Everolimus 5 mg Excipients q.s. Colour : Approved colours used
147.	**Vandetanib Tablets 100mg**	Each film coated tablets contains: Vandetanib 100 mg Excipients q.s. Colour : Approved colours used
148.	**Tofacitinib Tablets 5mg**	Each film coated tablets contains: Tofacitinib Citrate Eq. to Tofacitinib 5 mg Excipients q.s. Colour : Approved colours used
149.	**Bicalutamide Tablets USP 50mg**	Each film caoted tablet contains : Bicalutamide USP 50 mg Excipients q.s. Colour : Approved colours used
150.	**Bicalutamide Tablets USP 150mg**	Each film caoted tablet contains : Bicalutamide USP 150 mg Excipients q.s. Colour : Approved colours used
151.	**Abiraterone Acetate Tablets USP 500 mg**	Each uncoated tablet contains : Abiraterone Acetate USP 500 mg Excipients q.s.

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
152.	**Methotrexate Tablets BP 15 mg**	Each film coated tablet contains : Methotrexate BP 15 mg Excipients q.s. Colour : Approved colours used
153.	**Melphalan Tablets USP 2mg**	Each film coated tablet contains : Melphalan USP 2 mg Excipients q.s. Colour : Approved colours used
154.	**Ruxolitinib Tablets 15mg**	Each uncoated tablet contains : Ruxolitinib 15 mg Excipients q.s.
155.	**Tamoxifen Citrate Tablets USP 20 mg**	Each film coated tablet contains: Tamoxifen Citrate USP Eq. to Tamoxifen 20 mg Excipients q.s. Colour : Approved colours used
156.	**Tamoxifen Citrate Tablets USP 20 mg**	Each uncoated tablet contains: Tamoxifen Citrate USP Eq. to Tamoxifen 20 mg Excipients q.s.
157.	**Apalutamide Tablets 60mg**	Each film coated tablet contains : Apalutamide 60 mg Excipients q.s. Colour : Approved colours used
158.	**Everolimus Tablets 0.25mg**	Each film coated tablets contains: Everolimus 0.25 mg Excipients q.s. Colour : Approved colours used
159.	**Everolimus Tablets 0.5mg**	Each film coated tablets contains: Everolimus 0.5 mg Excipients q.s. Colour : Approved colours used
160.	**Everolimus Tablets 0.75mg**	Each film coated tablets contains: Everolimus 0.75 mg Excipients q.s. Colour : Approved colours used
161.	**Everolimus Tablets 1mg**	Each film coated tablets contains: Everolimus 1 mg Excipients q.s. Colour : Approved colours used

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
162.	**Everolimus Tablets 2.5mg**	Each film coated tablets contains: Everolimus 2.5 mg Excipients q.s. Colour : Approved colours used
163.	**Cabozantinib Tablets 20mg**	Each film coated tablet contains : Cabozantinib (S)-Malate Eq. to Cabozantinib 20 mg Excipients q.s. Colour : Approved colours used
164.	**Cabozantinib Tablets 40mg**	Each film coated tablet contains : Cabozantinib (S)-Malate Eq. to Cabozantinib 40 mg Excipients q.s. Colour : Approved colours used
165.	**Vinpocetine Tablets 5mg**	Each uncoated tablet contains : Vinpocetine 5 mg Excipients q.s.
166.	**Vinpocetine Tablets 10mg**	Each uncoated tablet contains : Vinpocetine 10 mg Excipients q.s.
167.	**Axitinib Tablets 5mg**	Each film coated tablet contains: Axitinib 5 mg Excipients q.s. Colour : Approved colours used
168.	**Cabozantinib Tablets 60mg**	Each film coated tablet contains : Cabozantinib (S)-Malate Eq. to Cabozantinib 60 mg Excipients q.s. Colour : Approved colours used
169.	**Palbociclib Tablets 75mg**	Each film coated tablet contains: Palbociclib 75 mg Excipients q.s. Colour : Approved colours used
170.	**Palbociclib Tablets 100mg**	Each film coated tablet contains: Palbociclib 100 mg Excipients q.s. Colour : Approved colours used
171.	**Palbociclib Tablets 125mg**	Each film coated tablet contains: Palbociclib 125 mg Excipients q.s. Colour : Approved colours used

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
172.	**Enzalutamide Tablets 160mg**	Each film coated tablet contains: Enzalutamide 160 mg Excipients q.s. Colour : Approved colours used
173.	**Vandetanib Tablets 300mg**	Each film coated tablet contains: Vandetanib 300 mg Excipients q.s. Colour : Approved colours used
174.	**Temozolomide Capsules 20 mg**	Each hard gelatin capsule contains : Temozolomide USP 20 mg Excipients q.s. Approved colour used in empty capsule shell
175.	**Temozolomide Capsules 100 mg**	Each hard gelatin capsule contains : Temozolomide USP 100 mg Excipients q.s. Approved colour used in empty capsule shell
176.	**Temozolomide Capsules 250 mg**	Each hard gelatin capsule contains : Temozolomide USP 250 mg Excipients q.s. Approved colour used in empty capsule shell
177.	**Hydroxyurea Capsules USP 500 mg**	Each hard gelatin capsule contains : Hydroxyurea USP 500 mg Excipients q.s. Approved colour used in empty capsule shell
178.	**Lenalidomide Capsules 15 mg**	Each hard gelatin capsule contains : Lenalidomide 15 mg Excipients q.s. Approved colour used in empty capsule shell
179.	**Sunitinib Maleate Capsules 50mg**	Each hard gelatin capsule contains : Sunitinib Maleate Eq. to Sunitinib 50 mg Excipients q.s. Approved colour used in empty capsule shell
180.	**Sunitinib Maleate Capsules 25mg**	Each hard gelatin capsule contains : Sunitinib Maleate Eq. to Sunitinib 25 mg Excipients q.s. Approved colour used in empty capsule shell
181.	**Sunitinib Maleate Capsules 12.5mg**	Each hard gelatin capsule contains : Sunitinib Maleate Eq. to Sunitinib 12.5 mg Excipients q.s. Approved colour used in empty capsule shell

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
182.	**Etoposide Capsules USP 100 mg**	Each hard gelatin capsule contains : Etoposide USP 100 mg Excipients q.s. Approved colour used in empty capsule shell
183.	**Nilotinib Capsules 200 mg**	Each hard gelatin capsule contains : Nilotinib 200 mg Excipients q.s. Approved colour used in empty capsule shell
184.	**Aprepitant Capsules USP 80 mg**	Each hard gelatin capsule contains : Aprepitant USP 80 mg Excipients q.s. Approved colour used in empty capsule shell
185.	**Aprepitant Capsules USP 125 mg**	Each hard gelatin capsule contains : Aprepitant USP 125 mg Excipients q.s. Approved colour used in empty capsule shell
186.	**Comiback of one capsule of Aprepitant Capsules USP 125 mg & two capsules of Aprepitant Capsules USP 80 mg**	**A)** Each hard gelatin capsule contains : Aprepitant USP 80 mg Excipients q.s. Approved colour used in empty capsule shell **B)** Each hard gelatin capsule contains : Aprepitant USP 125 mg Excipients q.s. Approved colour used in empty capsule shell
187.	**Imatinib Capsules 100 mg**	Each hard gelatin capsule contains : Imatinib Mesylate BP Eq. to Imatinib 100 mg Excipients q.s. Approved colour used in empty capsule shell
188.	**Imatinib Capsules 400 mg**	Each hard gelatin capsule contains : Imatinib Mesylate BP Eq. to Imatinib 400 mg Excipients q.s. Approved colour used in empty capsule shell
189.	**Nilotinib Capsules 150 mg**	Each hard gelatin capsule contains : Nilotinib 150 mg Excipients q.s. Approved colour used in empty capsule shell
190.	**Temozolomide Capsules USP 100 mg**	Each hard gelatin capsule contains : Temozolomide USP 100 mg Excipients q.s. Approved colour used in empty capsule shell

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
191.	**Etoposide Capsules USP 50 mg**	Each hard gelatin capsule contains : Etoposide USP 50 mg Excipients q.s. Approved colour used in empty capsule shell
192.	**Tretinoin Capsules 10mg**	Each hard gelatin capsule contains : Tretinoin USP 10 mg Excipients q.s. Approved colour used in empty capsule shell
193.	**Enzalutamide Capsules 40 mg**	Each hard gelatin capsule contains : Enzalutamide 40 mg Excipients q.s. Approved colour used in empty capsule shell
194.	**Procabazine Hydrochloride Capsules USP 50 mg**	Each hard gelatin capsule contains : Procabazine Hydrochloride USP Eq. to Procabazine 50 mg Excipients q.s. Approved colour used in empty capsule shell
195.	**Lenalidomide Capsules 5 mg**	Each hard gelatin capsule contains : Lenalidomide 5 mg Excipients q.s. Approved colour used in empty capsule shell
196.	**Lenalidomide Capsules 10 mg**	Each hard gelatin capsule contains : Lenalidomide 10 mg Excipients q.s. Approved colour used in empty capsule shell
197.	**Lenalidomide Capsules 25 mg**	Each hard gelatin capsule contains : Lenalidomide 25 mg Excipients q.s. Approved colour used in empty capsule shell
198.	**Lenvatinib Capsules 4mg**	Each hard gelatin capsule contains: Lenvatinib Mesylate Eq. to Lenvatinib 4 mg Excipients q.s. Approved colour used in empty capsule shell
199.	**Lenvatinib Capsules 10mg**	Each hard gelatin capsule contains: Lenvatinib Mesylate Eq. to Lenvatinib 10 mg Excipients q.s. Approved colour used in empty capsule shell

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
200.	**Pomalidomide Capsules 4mg**	Each hard gelatin capsule contains: Pomalidomide 4 mg Excipients q.s. Approved colour used in empty capsule shell
201.	**Thalidomide Capsule USP 50 mg**	Each hard gelatin capsule contains : Thalidomide USP 50 mg Excipients q.s. Approved colour used in empty capsule shell
202.	**Thalidomide Capsule USP 100 mg**	Each hard gelatin capsule contains : Thalidomide USP 100 mg Excipients q.s. Approved colour used in empty capsule shell
203.	**Hydroxycarbamide Capsules BP 500 mg**	Each hard gelatin capsule contains : Hydroxycarbamide BP 500 mg Excipients q.s. Approved colour used in empty capsule shell
204.	**Miltefosine Capsules 10mg**	Each hard gelatin capsule contains : Miltefosine 10 mg Excipients q.s. Approved colour used in empty capsule shell
205.	**Miltefosine Capsules 50mg**	Each hard gelatin capsule contains : Miltefosine 50 mg Excipients q.s. Approved colour used in empty capsule shell
206.	**Lomustine Capsules BP 40mg**	Each hard gelatin capsule contains : Lomustine BP 40 mg Excipients q.s. Approved colour used in empty capsule shell
207.	**Palbociclib Capsules 75mg**	Each hard gelatin capsule contains: Palbociclib 75 mg Excipients q.s. Approved colour used in empty capsule shell
208.	**Palbociclib Capsules 100mg**	Each hard gelatin capsule contains: Palbociclib 100 mg Excipients q.s. Approved colour used in empty capsule shell
209.	**Palbociclib Capsules 125mg**	Each hard gelatin capsule contains: Palbociclib 125 mg Excipients q.s. Approved colour used in empty capsule shell

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S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
210.	**Pomalidomide Capsules 2mg**	Each hard gelatin capsule contains: Pomalidomide 2 mg Excipients q.s. Approved colour used in empty capsule shell
211.	**Estramustine Phosphate Capsules 140mg**	Each hard gelatin capsule contains: Estramustine Sodium Phosphate Eq. to Estramustine Phosphate 140 mg Excipients q.s. Approved colour used in empty capsule shell

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