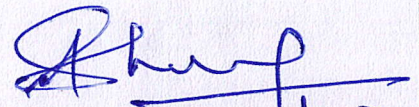


Date: 31/12/2025

FREE SALE CERTIFICATE

Certified that *M/s, Kwaliti 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.


31/12/25

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

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

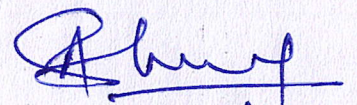
No. HFW-NZ (Drugs) 2025- 3918, Dated: Dharmshala, the 31/12/2025

Issued to:

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

Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
01.	Combipack of one vial Ifosfamide For Injection USP 1 gm/ Vial (As Lyophilized) 3 Ampoules of Mesna Injection 200mg / 2ml	Each vial contains : Ifosfamide USP 1 mg Excipients q.s. Each ml contains : Mesna BP 100 mg Water for Injection BP q.s.
02.	Bleomycin for Injection USP 15 IU / Vial (As Lyophilized)	Each vial contains : Bleomycin Sulfate USP Eq. to Bleomycin 15 IU
03.	Gemcitabine For Injection USP 200mg / Vial (As Lyophilized)	Each vial contains : Gemcitabine Hydrochloride USP Eq. to Gemcitabine 200 mg Excipients q.s.
04.	Gemcitabine For Injection USP 1000mg / Vial (As Lyophilized)	Each vial contains : Gemcitabine Hydrochloride USP Eq. to Gemcitabine 1000 mg Excipients q.s.
05.	Pemetrexed For Injection 100mg / Vial (As Lyophilized)	Each vial contains : Pemetrexed Disodium Eq. to Pemetrexed 100 mg Excipients q.s.
06.	Pemetrexed For Injection 500mg / Vial (As Lyophilized)	Each vial contains : Pemetrexed Disodium Eq. to Pemetrexed 500 mg Excipients q.s.
07.	Mitomycin For Injection USP 2mg / Vial (As Lyophilized)	Each vial contains : Mitomycin USP 2 mg Excipients q.s.
08.	Mitomycin For Injection USP 10mg / Vial (As Lyophilized)	Each vial contains : Mitomycin USP 10 mg Excipients q.s.
09.	Epirubicin Hydrochloride For Injection 50mg / Vial (As Lyophilized)	Each vial contains : Epirubicin Hydrochloride BP 50 mg Lactose BP 250 mg Methylparaben BP 10 mg (as freeze dried Powder)


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Asstt. Drugs Controller,
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Distt. Kangra at Dharmshala H.P. INDIA

No. HFW-NZ (Drugs) 2025- 3918, Dated: Dharmshala, the 31/12/2025

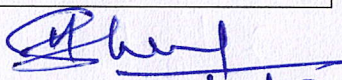
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Asstt. Drugs Controller Cum
Drug Licensing Authority
Distt. Kangra at Dharmshala (H.P)

Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
10.	Doxorubicin Hydrochloride For Injection BP 10mg / Vial (As Lyophilized)	Each vial contains : Doxorubicin Hydrochloride BP 10 mg Excipients q.s.
11.	Doxorubicin Hydrochloride For Injection BP 50mg / Vial (As Lyophilized)	Each vial contains : Doxorubicin Hydrochloride BP 50 mg Excipients q.s.
12.	Daunorubicin Hydrochloride For Injection 20mg / Vial (As Lyophilized)	Each vial contains : Daunorubicin Hydrochloride USP Eq. to Daunorubicin 20 mg Mannitol USP 100 mg
13.	Zoledronic Acid For Injection 4mg / Vial (As Lyophilized)	Each vial contains : Zoledronic acid monohydrate Eq. to Zoledronic acid anhydrous 4 mg Excipients q.s.
14.	Dactinomycin For Injection USP 500mcg / Vial (As Lyophilized)	Each vial contains : Dactinomycin USP 500 mcg Mannitol USP 100 mg
15.	Ifosfamide For Injection USP 1gm / Vial (As Lyophilized)	Each vial contains : Ifosfamide USP 1gm Excipients q.s.
16.	Bortezomib For Injection 2mg / Vial (As Lyophilized)	Each vial contains : Bortezomib 2 mg Excipients q.s.
17.	Vincristine Injection BP 1mg / Vial (As Lyophilized)	Each vial contains : Vincristine Sulphate BP 1 mg Excipients q.s.
18.	Vincristine Injection BP 2mg / Vial (As Lyophilized)	Each vial contains : Vincristine Sulphate BP 2 mg Excipients q.s.
19.	Cyclophosphamide For Injection BP 500mg / Vial (As Lyophilized)	Each vial contains : Cyclophosphamide BP Eq. to anhydrous cyclophosphamide 500 mg Excipients q.s.
20.	Cyclophosphamide For Injection BP 1000mg / Vial (As Lyophilized)	Each vial contains : Cyclophosphamide BP Eq. to anhydrous cyclophosphamide 1000 mg Excipients q.s.
21.	Melphalan For Injection BP 50mg / Vial (As Lyophilized)	Each vial contains : Melphalan BP 50 mg (Anhydrous) Excipients q.s.


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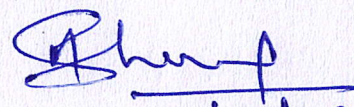
M/s, Kwaliti Pharmaceuticals Limited,
1-A Industrial Area, Raja Ka Bagh,
Tehsil Nurpur Himachal Pradesh, INDIA

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



Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
22.	Dacarbazine For Injection BP 200mg / Vial (As Lyophilized)	Each vial contains : Dacarbazine BP 200 mg Excipients q.s.
23.	Bendamustine Injection 100mg / Vial (As Lyophilized)	Each vial contains : Bendamustine Hydrochloride 100 mg Excipients q.s.
24.	Paclitaxel (protein - bound particles) for Injectable suspension 100mg / Vial (As Lyophilized)	Each vial contains : Paclitaxel BP 100 mg Human Albumin USP 900 mg
25.	Bortezomib For Injection 3.5mg / Vial (As Lyophilized)	Each vial contains : Bortezomib 3.5 mg Excipients q.s.
26.	Vincristine Sulfate For Injection USP 2mg / Vial (As Lyophilized)	Each vial contains : Vincristine Sulphate USP 2 mg Mannitol USP 100 mg
27.	Fludarabine Phosphate For Injection USP 50mg / Vial (As Lyophilized)	Each vial contains : Fludarabine Phosphate USP 50 mg Mannitol BP 100 mg
28.	Decitabine For Injection 50mg / Vial (As Lyophilized)	Each vial contains : Decitabine 50 mg Excipients q.s.
29.	Ganciclovir For Injection USP 500mg / Vial (As Lyophilized)	Each vial contains : Ganciclovir Sodium USP Eq. to Ganciclovir 500 mg Excipients q.s.
30.	Azacitidine For Injection 100mg / Vial (As Lyophilized)	Each vial contains : Azacitidine 100 mg Mannitol USP 100 mg
31.	Vincristine Sulfate For Injection USP 1mg / Vial (As Lyophilized)	Each vial contains : Vincristine Sulfate USP 1mg Mannitol USP 50 mg
32.	Vinblastine Sulfate For Injection USP 10mg / Vial (As Lyophilized)	Each vial contains : Vinblastine Sulfate USP 10 mg Excipients q.s.
33.	Leuprolide Acetate For Injection 3.75mg / Vial (As Lyophilized) (1 months depot)	Each vial contains : Leuprolide Acetate USP 3.75mg Excipients q.s.


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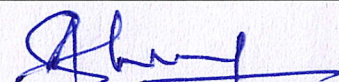
Issued to

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

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

Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
34.	Leuprolide Acetate For Injection 11.25mg / Vial (As Lyophilized) (3 months depot)	Each vial contains : Leuprolide Acetate USP 11.25mg Excipients q.s.
35.	Vinblastine Sulfate For Injection BP 10mg / Vial (As Lyophilized)	Each vial contains : Vinblastine Sulfate BP 10 mg Excipients q.s.
36.	Doxorubicin Hydrochloride For Injection USP 10mg / Vial (As Lyophilized)	Each vial contains : Doxorubicin Hydrochloride USP 10 mg Excipients q.s.
37.	Doxorubicin Hydrochloride For Injection USP 50mg / Vial (As Lyophilized)	Each vial contains : Doxorubicin Hydrochloride USP 50 mg Excipients q.s.
38.	Gemcitabine For Injection USP 1000mg / Vial (As Lyophilized)	Each vial contains : Gemcitabine Hydrochloride USP Eq. to Gemcitabine 1000 mg Excipients q.s.
39.	Daunorubicin Hydrochloride For Injection 50mg / Vial (As Lyophilized)	Each vial contains : Daunorubicin Hydrochloride USP Eq. to Daunorubicin 50 mg Excipients q.s.
40.	Daunorubicin Hydrochloride For Injection 20mg / Vial (As Lyophilized)	Each vial contains : Daunorubicin Hydrochloride USP Eq. to Daunorubicin 20 mg Excipients q.s.
41.	Epirubicin Hydrochloride For Injection 10mg / Vial (As Lyophilized)	Each vial contains : Epirubicin Hydrochloride BP 10 mg Lactose BP 50 mg Methylparaben BP 2 mg (as freeze dried Powder)
42.	Mitomycin Injection USP 40mg / Vial (As Lyophilized)	Each vial contains : Mitomycin USP 40 mg Excipients q.s.
43.	Cyclophosphamide For Injection USP 500mg / Vial (As Lyophilized)	Each vial contains : Cyclophosphamide USP Eq. to anhydrous Cyclophosphamide 500 mg Excipients q.s.
44.	Cyclophosphamide For Injection BP 500mg / Vial (As Lyophilized)	Each vial contains : Cyclophosphamide BP Eq. to anhydrous Cyclophosphamide 500 mg Excipients q.s.


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Asstt. Drugs Controller,
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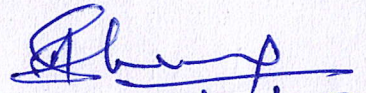
No. HFW-NZ (Drugs) 2025- 3918, Dated: Dharmshala, the 31/12/2025

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Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
45.	Oxaliplatin For Injection USP 50mg / Vial (As Lyophilized)	Each vial contains : Oxaliplatin USP 50 mg Excipients q.s.
46.	Oxaliplatin For Injection USP 100mg / Vial (As Lyophilized)	Each vial contains : Oxaliplatin USP 100 mg Excipients q.s.
47.	Carmustine For Injection USP 100mg / Vial (As Lyophilized)	Each vial contains : Carmustine USP 100 mg Excipients q.s.
48.	Dacarbazine For Injection USP 200mg / Vial (As Lyophilized)	Each vial contains : Dacarbazine USP 200 mg Excipients q.s.
49.	Vinblastine Sulfate For Injection BP 5mg / Vial (As Lyophilized)	Each vial contains : Vinblastine Sulfate BP 5 mg Excipients q.s.
50.	Mitomycin For Injection USP 20mg / Vial (As Lyophilized)	Each vial contains : Mitomycin USP 20 mg Excipients q.s.
51.	Gemcitabine For Injection USP 200mg/vial (As Lyophilized)	Each vial contains : Gemcitabine Hydrochloride USP Eq. to Gemcitabine 200 mg Excipients q.s.
52.	Gemcitabine For Injection USP 1000mg/vial (As Lyophilized)	Each vial contains : Gemcitabine Hydrochloride USP Eq. to Gemcitabine 1000 mg Excipients q.s.
53.	Thiotepa For Injection USP (As Lyophilized)	Each vial contains : Thiotepa USP 100 mg Excipients q.s.
55.	Trastuzumab For Injection 440mg/ vial (As Lyophilized)	Each vial contains : Trastuzumab 440 mg Excipients q.s.
56.	Trastuzumab For Injection 150mg/ vial (As Lyophilized)	Each vial contains : Trastuzumab 150 mg Excipients q.s.
57.	Cyclophosphamide For Injection USP 1000mg / Vial (As Lyophilized)	Each vial contains : Cyclophosphamide USP Eq. to anhydrous Cyclophosphamide 1000 mg Excipients q.s.


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Asstt. Drugs Controller,
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Distt. Kangra at Dharmshala H.P. INDIA

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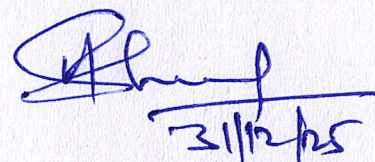
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Asstt. Drugs Controller Cum
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Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
58.	Cyclophosphamide For Injection USP 200mg / Vial (As Lyophilized)	Each vial contains : Cyclophosphamide USP Eq. to anhydrous Cyclophosphamide 200 mg Excipients q.s.
59.	Leuprolide Acetate For Injection 22.5 mg / Vial (As Lyophilized) (3 months depot)	Each vial contains : Leuprolide Acetate USP 22.5mg Excipients q.s.
60.	L- Asparaginase for Injcetion 10000 K.U. / Vial (As Lyophilized)	Each vial contains : L- Asparaginase 10000 K.U.
61.	L- Asparaginase for Injcetion 5000 K.U. / Vial (As Lyophilized)	Each vial contains : L- Asparaginase 5000 K.U.
62.	Octreotide Acetate Long Acting Release Injection 20mg/vial (As Lyophilized)	Each vial contains : Octreotide Acetate USP Eq. to Octreotide 20 mg Excipients q.s.
63.	Epirubicin Hydrochloride For Injection 50mg / Vial (As Lyophilized)	Each vial contains : Epirubicin Hydrochloride BP 50 mg Excipients q.s.
64.	Epirubicin Hydrochloride For Injection 10mg / Vial (As Lyophilized)	Each vial contains : Epirubicin Hydrochloride BP 10 mg Excipients q.s.
65.	L- Asparaginase for Injection 5000 IU / Vial (As Lyophilized)	Each vial contains : L- Asparaginase 5000 IU
66.	Fludarabine Phosphate For Injection USP 50mg / Vial (As Lyophilized)	Each vial contains : Fludarabine Phosphate USP 50 mg Mannitol USP 100 mg
67.	Combipack of one vial Ifosfamide For Injection USP 2 gm/ Vial (As Lyophilized) 6 Ampoules of Mesna Injection 200mg / 2ml	Each vial contains : Ifosfamide USP 2 mg Excipients q.s. Each ml contains : Mesna USP 100 mg Water for Injection USP q.s.



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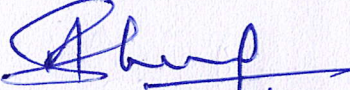
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Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
68.	Combipack of one vial Ifosfamide For Injection USP 1 gm/ Vial (As Lyophilized) 3 Ampoules of Mesna Injection 200mg / 2ml	Each vial contains : Ifosfamide USP 1 mg Excipients q.s. Each ml contains : Mesna USP 100 mg Water for Injection USP q.s.
69.	Dactinomycin For Injection USP (As Lyophilized)	Each vial contains : Dactinomycin USP 500 mcg Mannitol USP 20 mg
70.	Bleomycin for Injection USP 15 Units (As Lyophilized)	Each vial contains : Bleomycin Sulfate USP Eq. to Bleomycin 15 Units
71.	Pemetrexed For Injection 500mg / Vial (As Lyophilized)	Each vial contains : Pemetrexed Disodium USP Eq. to Pemetrexed 500 mg Excipients q.s.
72.	Triptorelin For Injection 3.75mg/Vial (As Lyophilized)	Each vial contains: Triptorelin Acetate Eq. to Triptorelin 3.75 mg
73.	Triptorelin For Injection 11.25mg/Vial (As Lyophilized)	Each vial contains: Triptorelin Acetate Eq. to Triptorelin 11.25 mg
74.	Leuprolide Acetate For Injection 7.5 mg / Vial (As Lyophilized) (1 month depot)	Each vial contains : Leuprolide Acetate USP 7.5 mg Excipients q.s.
75.	Idarubicin Hydrochloride For Injection USP 5mg/vial (As Lyophilized)	Each vial contains: Idarubicin Hydrochloride USP 5 mg Excipients q.s.
76.	Ixabepilone For Injection 15mg (As Lyophilized)	Each vial contains : Ixabepilone 15 mg
77.	Ixabepilone For Injection 45mg (As Lyophilized)	Each vial contains : Ixabepilone 45 mg


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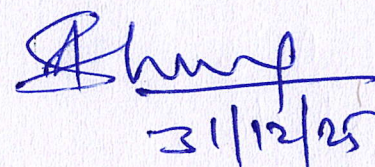
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Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
78.	Trabectedin powder for concentrate for solution for infusion 1mg/vial (As Lyophilized)	Each vial contains : Trabectedin 1 mg
79.	Dacarbazine For Injection USP 100mg/vial (As Lyophilized)	Each vial contains : Dacarbazine USP 100 mg Excipients q.s.
80.	Leuprolide Acetate For Injection 3.75mg / Vial (As Lyophilized) (1 month depot)	A) Each vial contains : Leuprolide Acetate USP 3.75mg Excipients q.s. In Combipack with 2ml ampoule (diluent) B) Each ml contains : Carboxymethylcellulose Sodium USP 0.625 mg Mannitol USP 50 mg Polysorbate 80 USP 5 mg Water for Injection USP q.s.
81.	Leuprolide Acetate For Injection 11.25mg / Vial (As Lyophilized) (3 months depot)	A) Each vial contains : Leuprolide Acetate USP 11.25mg Excipients q.s. In Combipack with 2ml ampoule (diluent) B) Each ml contains : Carboxymethylcellulose Sodium USP 0.625 mg Mannitol USP 50 mg Polysorbate 80 USP 5 mg Water for Injection USP q.s.
82.	Leuprolide Acetate For Injection 22.5mg / Vial (As Lyophilized) (3 months depot)	A) Each vial contains : Leuprolide Acetate USP 22.5mg Excipients q.s. In Combipack with 2ml ampoule (diluent) B) Each ml contains : Carboxymethylcellulose Sodium USP 0.625 mg Mannitol USP 50 mg Polysorbate 80 USP 5 mg Water for Injection USP q.s.
83.	Zoledronic Acid For Injection 4mg / Vial (As Lyophilized)	Each vial contains : Zoledronic acid monohydrate Eq. to Zoledronic acid anhydrous 4 mg Excipients q.s. In Combipack with Sterile water for injection USP



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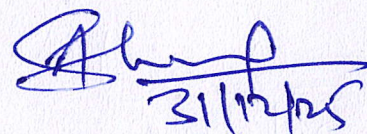
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Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
84.	Doxorubicin Hydrochloride Liposomal For Injection 20mg/vial (As Lyophilized)	Each vial contains : Doxorubicin hydrochloride BP 20mg (as pegylated liposomal) Excipients q.s.
85.	Leucovorin Calcium For Injection USP 50mg/ vial (As Lyophilized)	Each vial contains : Leucovorin Calcium USP Eq. to Leucovorin 50mg Excipients q.s.
86.	Leucovorin Calcium For Injection USP 100mg/ vial (As Lyophilized)	Each vial contains : Leucovorin Calcium USP Eq. to Leucovorin 100mg Excipients q.s.
87.	Calcium Folate For Injection BP 50mg/vial (As Lyophilized)	Each vial contains : Calcium Folate BP Eq. to Folinic Acid 50 mg Excipients q.s.
88.	Calcium Folate For Injection BP 100mg/vial (As Lyophilized)	Each vial contains : Calcium Folate BP Eq. to Folinic Acid 100 mg Excipients q.s.
89.	Idarubicin Hydrochloride For Injection USP 5mg/vial (As Lyophilized)	Each vial contains: Idarubicin Hydrochloride USP 5 mg Excipients q.s. In combipack with Sterile water for Injection USP 5ml
90.	Triptorelin for injection 22.5mg/Vial (As Lyophilized)	Each vial contains : Triptorelin Pamoate Eq. to Triptorelin Acetate 22.5 mg
91.	Bendamustine Hydrochloride for Injection USP 25 mg (As Lyophilized)	Each vial contains : Bendamustine Hydrochloride USP 25mg Excipients q.s.
92.	Bendamustine Hydrochloride for Injection USP 100 mg (As Lyophilized)	Each vial contains : Bendamustine Hydrochloride USP 100mg Excipients q.s.
93.	Combipack of one vial Ixabepilone For Injection 15mg & One vial of Diluent for Ixabepilone 8 ml (As Lyophilized)	A) Each vial contains: Ixabepilone 15 mg B) Each Diluent for Ixabepilone vial (8ml deliverable volume) contains: Polyoxyethylated castor oil 52.8% w/v Dehydrated Alcohol USP 39.8% w/v



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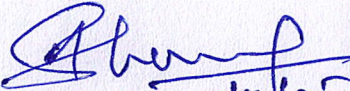
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Free Sale Certificate**Annexure -A**

S. No.	GENERIC NAME & DOSAGE FORM	COMPOSITION
94.	Dexrazoxane for Injection 500mg/vial (As Lyophilized)	Each vial contains : Dexrazoxane hydrochloride Eq. to Dexrazoxane 500 mg Excipients q.s.
95.	Triptorelin Pamoate For Injectable Suspension 3.75mg/ vial (As Lyophilized)	Each vial contains : Triptorelin Pamoate 3.75 mg Excipients q.s.
96.	Triptorelin Pamoate For Injectable Suspension 11.25mg/ vial (As Lyophilized)	Each vial contains : Triptorelin Pamoate 11.25 mg Excipients q.s.
97.	Triptorelin Pamoate For Injectable Suspension 22.5mg/ vial (As Lyophilized)	Each vial contains : Triptorelin Pamoate 22.5 mg Excipients q.s.
98.	Idarubicin Hydrochloride For Injection 10mg/vial (As Lyophilized)	Each vial contains: Idarubicin Hydrochloride USP 10 mg Excipients q.s.
99.	Ganciclovir For Injection USP 500mg / Vial (As Lyophilized)	Each vial contains : Ganciclovir Sodium USP Eq. to Ganciclovir 500 mg
100.	Bortezomib For Injection 1mg (As Lyophilized)	Each vial contains : Bortezomib 1mg Excipients q.s.
101.	Carfilzomib For Injection 60mg/vial (As Lyophilized)	Each vial contains: Carfilzomib 60mg Excipients q.s.
102.	Ifosfamide For Injection USP 2gm / Vial (As Lyophilized)	Each vial contains : Ifosfamide USP 2gm Excipients q.s.


31/12/25

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

No. HFW-NZ (Drugs) 2025- 3918, Dated: Dharmshala, the 31/12/2025

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