

**HEALTH & FAMILY WELFARE DEPARTMENT  
HIMACHAL PRADESH**

**Certificate of Good Manufacturing Practices**

This one page certificate conforms to the format recommended by the World Health Organization [General Instructions and Explanatory Notes attached].

**Certificate No. HFW-H(Drugs)57/2016**

**On the basis of the inspection carried out on 26<sup>th</sup> & 27<sup>th</sup> February 2020 and 12<sup>th</sup> & 13<sup>th</sup> January 2021, we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table I:**

1. Names and Address of Site: **M/s Kwaliti Pharmaceuticals Ltd.,  
Plot No. 1-A, Industrial Area,  
Raja Ka Bagh, Distt. Kangra 176201  
Himachal Pradesh.**
2. Manufacturer's License No: **NNZ/08/40 & BNZ/08/41 on Form 25 & 28  
Valid upto 27.12.2025.**
3. Table-I:

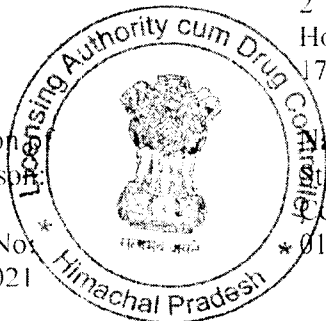
Dosage Form[s]	Category[ies]	Activity[ies]
Tablets, Capsule, Liquid Injections and Lyophilized Injections	Cytotoxic Drugs	Production, Packing & Quality Control

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 **16.02.2024**. 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: **State Drugs Controller,  
Controlling -cum -Licensing Authority,  
2<sup>nd</sup> floor, Himuda Commercial Complex, Phase-I,  
Housing Board, Baddi, Distt. Solan [H.P.]  
173205, INDIA.**

Name & Function: **Navneet Marwaha**  
Responsible person: **State Drugs Controller**  
Controlling cum Licensing Authority  
Telephone/Fax No: **01795-244288. sdc4hp@gmail.com**  
Date: **17/02/2021**



Signature:  
Stamp:

**(NAVNEET MARWAHA)**  
State Drugs Controller  
Controlling cum Licensing Authority  
Baddi Distt. Solan (H. P.) 173205  
01795-244288 sdc4hp@gmail.com

17-2-21

### 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 certificate number should be traceable within the regulatory authority issuing the certificate.
- 3 Where the Regulatory Authority issues a license for the Site, this number should be specified. Record "Not Applicable" in cases where there is no legal framework for the issuing of a license.
- 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	Packaging
	Hormone	Production, Packing, Quality Control
	Penicillin	Repackaging and Labeling
Injectables	Cephalosporin	Aseptic preparation, Packaging, Labeling

#### **Example 2**

Pharmaceutical Product[s] 1	Category [ies]	Activity [ies]
Starting Material [s]		
Paracetamol	Analgesic	Synthesis, Purification, packing, Labeling

Use, whenever available, International Non proprietary Names [Inns] or otherwise national Non proprietary 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.

**Food & Drug Administration, Punjab,  
Near Civil Hospital, Kharar, District Sahibzada Ajit Singh Nagar (**

To,

M/s Kwaliti Pharmaceuticals Ltd.,  
Village Nag Kalan, Majitha Road,  
Amritsar (Punjab)

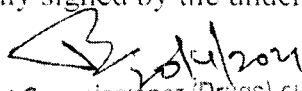
No.Drugs(01)/Pb.2021/2081  
Dated: 20/4/2021

**Subject: Application for grant of GMP certificate and certificate of  
Pharmaceuticals products (COPP)**

Reference your application date 15.03.2021 and Letter No. NZ/BD-SZO/PUN/COPP/KP/001/4490-4492 dated 15.03.2021 of deputy controller India, CDSCO (Baddi) Container Corporation of India building, Village Sheetalpur, Tehsil Baddi, District Solan regarding subject cited above.

As per your application and as per recommendation of deputy drugs controller India, CDSCO (Baddi), village Sheetalpur, Tehsil Baddi, District Solan (HP) under reference, Please find enclosed herewith, the GMP certificate and certificates of Pharmaceuticals products (COPP) for 402 products duly signed by the undersigned.

Encl: GMP certificates & 402 COPPS


  
Assistant Commissioner (Drugs)-cum-  
Licensing Authority, FDA Punjab,  
Near Civil Hospital Kharar-140301,  
District Sahibzada Ajit Singh Nagar.

No.Drugs(01)/Pb.2021

Dated:

Copy of above is forwarded to:

- (i) The Deputy Drug Controller India, CDSCO (Baddi), Village Sheetalpur, Tehsil Baddi, District Solan (HP) (Copies of COPP certificate are attached).
- (ii) The Drug Inspector, Amritsar for Information

  
Assistant Commissioner (Drugs)-cum-  
Licensing Authority, FDA Punjab,  
Near Civil Hospital Kharar-140301,  
District Sahibzada Ajit Singh Nagar.

**Food & Drug Administration, Punjab,**  
Near Civil Hospital, Kharar, District Sahibzada Ajit Singh Nagar

**Certificate of Good Manufacturing Practices**

(This one page certificate confirms to the format recommended by the World Health Organisation as per WHO Technical Report Series, No. 908, 2003).

Certificate No. : 6085/2021

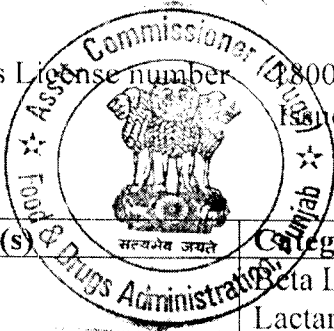
Dated: 22/4/2021

On the basis of the Joint Inspection made by Drugs Inspectors of CDSCO (Sub Zone Baddi) and Drugs Inspectors of State on 18<sup>th</sup> & 19<sup>th</sup> March 2021, it is certified that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories & activities listed in Table 1.

1. Name and address of site: M/s Kwaliti Pharmaceuticals Limited,  
Situating at 6<sup>th</sup> mile stone, Village Nag Kalan,  
Majitha Road, Amritsar-143601 Punjab  
(India).

2. Manufacturer's License number: 1800-OSP (Form 25) & 1804-B (Form 28)  
Issued on 15-02-2016 & valid up to 27-12-2025.

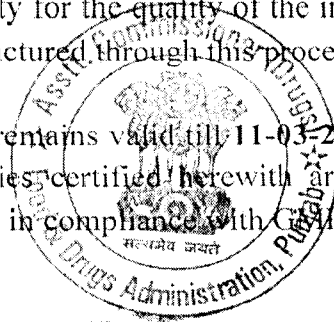
3. Table 1 :



Dosage Form (s)	Category (ies)	Activity (ies)
Tablets	Beta Lactam & Non Beta Lactam	Formulations
Hard Gelatin Capsules	Beta Lactam & Non Beta Lactam	Formulations
Oral Liquids Preparations	-	Formulations
Small Volume Parenteral	Non Beta Lactam	Formulations
Sterile Powders for injection	Beta Lactam & Non Beta Lactam	Formulations
External Preparation (Cream, Ointment, Liquid External and Lotions)	-	Formulations
Dry powder for oral suspension	Beta Lactam & Non Beta Lactam	Formulations
Powder for oral use	Non Beta Lactam	Formulations
Sterile Ophthalmic Solution	Non Beta Lactam	Formulations
Suppositories	-	Formulations

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 till ~~11-03-2024~~, 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.



*[Signature]*  
Assistant Commissioner (Drugs) cum-  
Executive Officer, F&DA Punjab,  
Near Civil Hospital, Kharar, District  
Sahibzada, Ajit Singh Nagar, Punjab-140001,  
India.

**Address of certifying authority:** Assistant Commissioner (Drugs),  
Food & Drugs Administration, Punjab,  
Near Civil Hospital, Kharar, District  
Sahibzada, Ajit Singh Nagar (Punjab), India  
Email: [punjabdrugscontrolorg@gmail.com](mailto:punjabdrugscontrolorg@gmail.com)

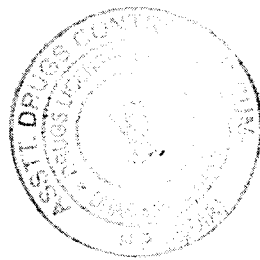
**Name and function of responsible person:** Sh. Dinesh Kumar  
**Date:** Assistant Commissioner (Drugs)  
Email: [punjabdrugscontrolorg@gmail.com](mailto:punjabdrugscontrolorg@gmail.com)


Date: 23/2/2021

**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 **28.12.2020** and is renewed up- to **27.12.2025**, 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.



  
(Ashish Raina)  
Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

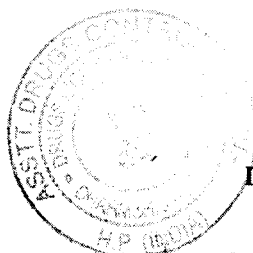
No. HFW-NZ (Drugs) 2021- 302, Dated: Dharmshala, the 23/02/2021

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.	Oxaliplatin For Injection	Each ml contains: Oxaliplatin BP 2 mg Water for Injection BP q.s.
02.	Methotrexate Injection BP 1000 mg / 10ml	Each ml contains: Methotrexate BP 100 mg Water for Injection BP q.s.
03.	Methotrexate Injection BP	Each ml contains: Methotrexate BP 2.5 mg Water for Injection BP q.s.
04.	Tretinoin Capsules 10mg	Each hard gelatin capsule contains : Tretinoin 10 mg Excipients q.s. Approved colour used in empty capsule shell
05.	Thiotepa For Injection USP	Each vial contains : Thiotepa USP 100 mg Excipients q.s.
06.	Fludarabine Phosphate Tablets 10mg	Each film coated tablet contains: Fludarabine Phosphate USP 10 mg Excipients q.s. Colour : Approved colours used
07.	Fulvestrant Injection	Each ml contains: Fulvestrant BP 50 mg Water for Injection BP q.s.
08.	Bevacizumab Injection 100mg/ 4ml	Each ml contains: Bevacizumab 25 mg Water for Injection BP q.s.
09.	Bevacizumab Injection 400mg/ 16ml	Each ml contains: Bevacizumab 25 mg Water for Injection BP q.s.
10.	Trastuzumab For Injection 440 mg / vial (As Lyophilized)	Each vial contains : Trastuzumab 440 mg Excipients q.s.



*(Signature)*  
(Ashish Raina)

Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

No. HFW-NZ (Drugs) 2021- 302, Dated: Dharmshala, the 27/2/2021

Issued to:

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

**Free Sale Certificate**

**Annexure - A**

11.	<b>Trastuzumab For Injection 150 mg / vial (As Lyophilized)</b>	Each vial contains : Trastuzumab 150 mg Excipients q.s.
12.	<b>Azathioprine Tablets USP 50mg</b>	Each film coated tablet contains: Azathioprine USP 50 mg Excipients q.s. Colour : Approved colours used
13.	<b>Chlorambucil Tablets USP 2mg</b>	Each film coated tablet contains: Chlorambucil USP 2 mg Excipients q.s. Colour : Approved colours used
14.	<b>Daunorubicin Liposomal Injection 50mg/ 25ml</b>	Each ml contains: Daunorubicin Citrate Eq. to Daunorubicin 2 mg Water for Injection BP q.s.
15.	<b>Methotrexate Injection BP</b>	Each ml contains: Methotrexate BP 25 mg Sodium Hydroxide BP q.s. Water for Injection BP q.s.
16.	<b>Cytrabine Injection BP</b>	Each ml contains: Cytrabine BP 20 mg Water for Injection BP q.s.



*(Signature)*  
(Ashish Raina)

Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

No. HFW-NZ (Drugs) 2021- 302, Dated: Dharmshala, the 23/2/2021

Issued to:

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

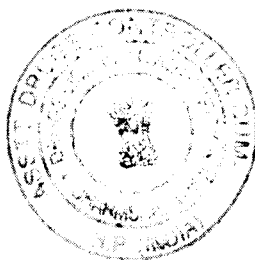



Date: 26/03/2021

**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 **28.12.2020** and is renewed up- to **27.12.2025**, 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.



  
(Ashish Raina)  
Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

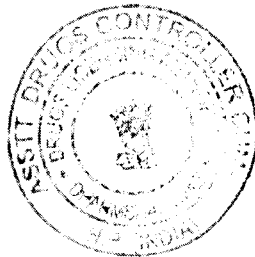
No. HFW-NZ (Drugs) 2021- 675 Dated: Dharmshala, the 26/03/2021

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.	Oxaliplatin Injection USP 50mg/ 25ml	Each ml contains: Oxaliplatin BP 2 mg Water for Injection BP q.s.
02.	Oxaliplatin Injection USP 100mg/ 50ml	Each ml contains: Oxaliplatin BP 2 mg Water for Injection BP q.s.
03.	Epirubicin Injection BP 10mg/ 5ml	Each ml contains: Epirubicin Hydrochloride BP 2 mg Water for Injection BP q.s.
04.	Epirubicin Injection BP 50mg/ 25ml	Each ml contains: Epirubicin Hydrochloride BP 2 mg Water for Injection BP q.s.
05.	Carboplatin Injection BP 150mg/ 15ml	Each ml contains: Carboplatin BP 10 mg Water for Injection BP q.s.
06.	Carboplatin Injection BP 450mg/ 45ml	Each ml contains: Carboplatin BP 10 mg Water for Injection BP q.s.
07.	Cisplatin Injection BP 10mg/ 10ml	Each ml contains: Cisplatin BP 1 mg Water for Injection BP q.s.
08.	Cisplatin Injection BP 50mg/ 50ml	Each ml contains: Cisplatin BP 1 mg Water for Injection BP q.s.
09.	Cytarabine Injection BP 100 mg/ ml	Each ml contains: Cytarabine BP 100 mg Water for Injection BP q.s.
10.	Calcium Folate Injection BP 50 mg/ 5ml	Each ml contains: Calcium Folate BP Eq. to Folate Acid 10 mg Water for Injection BP q.s.



*(Signature)*  
(Ashish Rana)  
Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

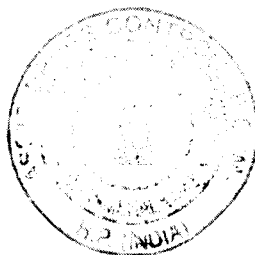
No. HFW-NZ (Drugs) 2021- 675 Dated: Dharmshala, the 26/03/2021

Issued to:

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

**Free Sale Certificate  
Annexure -A**

11.	Leucovorin Calcium Injection USP 50 mg/ 5ml	Each 5ml contains: Leucovorin Calcium USP Eq. to Leucovorin 50 mg Water for Injection USP q.s.
12.	Etoposide Injection USP 100 mg / 5ml	Each ml contains: Etoposide USP 20 mg Benzyl Alcohol (As Preservative) USP 30 mg Ethyl Alcohol USP 30.50% v/v
13.	Doxorubicin Hydrochloride Liposome Injection (As Pegylated Liposome ) 20 mg / 10 ml	Each ml contains: Doxorubicin Hydrochloride BP 2 mg (As Pegylated Liposome) Water for Injection BP q.s.
14.	Docetaxel Injection USP 20 mg/ 0.5 ml  Solvent For Docetaxel Injection USP 20 mg/ 0.5 ml ( Only For Export)	Each single dose vial contains: Docetaxel Trihydrate USP Eq. to anhydrous Docetaxel 20 mg Polysorbate 80 USP q.s. to 0.5 ml  Each vial contains: Alcohol (95 % v/v ) (Absolute Alcohol content 15.25 % v/v) USP 13% w/v Water for Injection USP q.s. to 1.5 ml
15.	Docetaxel Injection USP 80 mg/ 2 ml  Solvent For Docetaxel Injection USP 80 mg/ 2 ml ( Only For Export)	Each single dose vial contains: Docetaxel Trihydrate USP Eq. to anhydrous Docetaxel 80 mg Polysorbate 80 USP q.s. to 2 ml  Each vial contains: Alcohol (95 % v/v ) (Absolute Alcohol content 15.25 % v/v) USP 13% w/v Water for Injection USP q.s. to 6 ml
16.	Docetaxel Injection USP 120 mg/ 3 ml  Solvent For Docetaxel Injection USP 120 mg/ 3 ml ( Only For Export)	Each single dose vial contains: Docetaxel Trihydrate USP Eq. to anhydrous Docetaxel 120 mg Polysorbate 80 USP q.s. to 3 ml  Each vial contains: Alcohol (95 % v/v ) (Absolute Alcohol content 15.25 % v/v) USP 13% w/v Water for Injection USP q.s. to 9 ml



*(Signature)*  
(Ashish Raina)  
Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

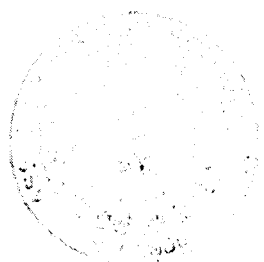
No. HFW-NZ (Drugs) 2021- 675 Dated: Dharmshala, the 26/03/2021

Issued to:

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

**Free Sale Certificate**  
**Annexure - A**

17.	<b>Vinorelbine Injection USP</b> 10 mg/ ml	Each ml contains: Vinorelbine Tartrate USP Eq. to Vinorelbine 10 mg Water for Injection BP q.s.
18.	<b>Paclitaxel Injection USP</b> 30 mg/ 5ml	Each ml contains: Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP 527 mg Dehydrated Alcohol USP 49.70% v/v
19.	<b>Paclitaxel Injection USP</b> 100 mg/ 16.7ml	Each ml contains: Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP 527 mg Dehydrated Alcohol USP 49.70% v/v
20.	<b>Paclitaxel Injection USP</b> 260 mg/ 43.4ml	Each ml contains: Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP 527 mg Dehydrated Alcohol USP 49.70% v/v
21.	<b>Paclitaxel Injection USP</b> 300 mg/ 50ml	Each ml contains: Paclitaxel USP 6 mg Polyoxyl 35 Castor Oil USP 527 mg Dehydrated Alcohol USP 49.70% v/v
22.	<b>Methotrexate Injection BP</b> 50 mg/ 2 ml	Each ml contains: Methotrexate BP 25 mg Water for Injection BP q.s.
23.	<b>Doxorubicin Hydrochloride Liposome Injection (As Pegylated Liposome)</b> 50 mg / 25 ml	Each ml contains: Doxorubicin Hydrochloride BP 2 mg (As Pegylated Liposome) Water for Injection BP q.s.
24.	<b>Pagaspargase Injection</b> 3750 IU /5ml	Each 5ml contains: Pegaspargase 3750 IU (Pegylated L-Asperaginase)
25.	<b>Cytarabine Injection BP</b> 100 mg/ 5 ml	Each ml contains: Cytarabine BP 20 mg Water for Injection BP q.s.
26.	<b>Vincristine sulfate for injection USP</b> 2mg / 2ml	Each ml contains: Vincristine sulfate USP 1 mg Water for Injection USP q.s.



*(Signature)*  
(Ashish Raina)

Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

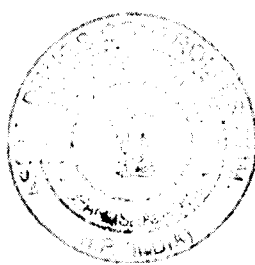
No. HFW-NZ (Drugs) 2021- 675 , Dated: Dharmshala, the 26/03/2021

Issued to:

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

**Free Sale Certificate  
Annexure -A**

27.	<b>Vinorelbine Injection USP 50mg/5ml</b>	Each ml contains: Vinorelbine Tartrate USP Eq. to Vinorelbine 10 mg Water for Injection BP q.s.
28.	<b>Topotecan Injection Concentrate 4mg/4ml</b>	Each ml contains: Topotecan Hydrochloride Eq. to Topotecan 1 mg Water for Injection BP q.s.
29.	<b>Cladribine Injection USP 10mg/10ml</b>	Each ml contains: Cladribine USP 1 mg Sodium Chloride BP 9 mg Water for Injection BP q.s.
30.	<b>Paclitaxel Injection USP 260mg/43.4ml</b>	Each ml contains: Paclitaxel USP 6 mg Polyoxyl 35 Caster oil USP NF 527 mg Dehydrate Alcohol USP 49.70% v/v
31.	<b>Carboplatin Injection BP 450mg/45ml</b>	Each ml contains: Carboplatin BP 10 mg Water for Injection BP q.s.
32.	<b>Vinorelbine Injection USP 50mg/5ml</b>	Each ml contains: Vinorelbine Tartrate USP Eq. to Vinorelbine 10 mg Water for Injection BP q.s.
33.	<b>Fluorouracil Injection BP 500 mg/ 10 ml</b>	Each ml contains: Fluorouracil BP 50 mg Sodium Hydroxide BP 10 mg Water for Injection BP q.s.
34.	<b>Docetaxel Injection USP 40 mg/ ml</b>  <b>Solvent For Docetaxel Injection USP 40 mg/ ml ( Only For Export)</b>	Each single dose vial contains: Docetaxel Trihydrate USP Eq. to anhydrous Docetaxel 40 mg Polysorbate 80 USP q.s. to 1 ml  Each vial contains: Alcohol (95 % v/v ) (Absolute Alcohol content 15.25 % v/v) USP 13% w/v Water for Injection USP q.s. to 3 ml



*(Signature)*  
26/3/21

**(Ashish Raina)**  
Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

No. HFW-NZ (Drugs) 2021- 675, Dated: Dharmshala, the 26/03/2021

Issued to:

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

**Free Sale Certificate**  
**Annexure -A**

35.	<b>Goserelin Acetate Injection</b> 3.6 mg/ ml	Each ml contains: Goserelin Acetate Eq. to Goserelin 3.6 mg Water for Injection BP q.s.
36.	<b>Carboplatin Injection BP</b> 50 mg/ 5ml	Each ml contains: Carboplatin BP 10 mg Water for Injection BP q.s.
37.	<b>Irinotecan Hydrochloride Injection USP</b> 40mg/ 2ml	Each ml contains: Irinotecan Hydrochloride USP 20 mg Water for Injection BP q.s.
38.	<b>Docetaxel Injection</b> 120 mg/ 3 ml  <b>Solvent For</b> <b>Docetaxel Injection</b> 120 mg/ 3 ml <b>( Only For Export)</b>	Each single dose vial contains: Docetaxel Trihydrate BP Eq. to anhydrous Docetaxel 120 mg Polysorbate 80 BP q.s. to 3 ml  Each vial contains: Alcohol (95 % v/v ) (Absolute Alcohol content 15.25 % v/v) BP 13% w/v Water for Injection BP q.s. to 9 ml
39.	<b>Leucovorin Calcium Injection USP</b> 10 mg/ ml	Each ml contains: Leucovorin Calcium USP Eq. to Leucovorin 10 mg Water for Injection USP q.s.
40.	<b>Vinblastin Sulphate Injection BP</b> 5mg/5ml	Each ml contains: Vinblastin Sulphate USP 1 mg Sodium Chloride USP 9 mg Benzyl Alcohol USP 0.9 % v/v Water for Injection USP q.s.
41.	<b>Docetaxel Injection USP</b> 40 mg/ 2 ml	Each ml contains: Docetaxel Anhydrous USP 20mg Citric Acid Anhydrous USP 4 mg Polysorbate 80 USP 520 mg Dehydrated Alcohol USP 395 mg



*(Signature)*  
(Ashish Raina) 26/3/21

Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

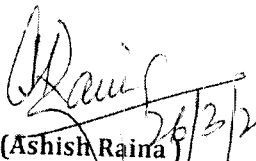
No. HFW-NZ (Drugs) 2021- 675, Dated: Dharmshala, the 26/03/2021

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42.	<b>Docetaxel Injection USP 80 mg/ 4ml</b>	Each ml contains: Docetaxel Anhydrous USP 20mg Citric Acid Anhydrous USP 4 mg Polysorbate 80 USP 520 mg Dehydrated Alcohol USP 395 mg
43.	<b>Docetaxel Injection USP 120 mg/ 6ml</b>	Each ml contains: Docetaxel Anhydrous USP 20mg Citric Acid Anhydrous USP 4 mg Polysorbate 80 USP 520 mg Dehydrated Alcohol USP 395 mg
44.	<b>Oxaliplatin Injection USP 100mg/ 20ml</b>	Each ml contains: Oxaliplatin USP 5mg Water for Injection USP q.s.
45.	<b>Oxaliplatin Injection USP 200mg/ 40ml</b>	Each ml contains: Oxaliplatin USP 5mg Water for Injection USP q.s.
46.	<b>Docetaxel Injection 20 mg/ 0.5 ml</b>  <b>Solvent For Docetaxel Injection 20 mg/ 0.5 ml ( Only For Export)</b>	Each single dose vial contains: Docetaxel Trihydrate BP Eq. to anhydrous Docetaxel 20 mg Polysorbate 80 BP q.s. to 0.5 ml  Each vial contains: Alcohol (95 % v/v ) (Absolute Alcohol content 15.25 % v/v) BP 13% w/v Water for Injection BP q.s. to 1.5 ml
47.	<b>Docetaxel Injection 80 mg/ 2 ml</b>  <b>Solvent For Docetaxel Injection 80 mg/ 2 ml ( Only For Export)</b>	Each single dose vial contains: Docetaxel Trihydrate BP Eq. to anhydrous Docetaxel 80 mg Polysorbate 80 BP q.s. to 2 ml  Each vial contains: Alcohol (95 % v/v ) (Absolute Alcohol content 15.25 % v/v) BP 13% w/v Water for Injection BP q.s. to 6 ml

  
(Ashish Raina)

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Distt. Kangra at Dharmshala H.P. INDIA

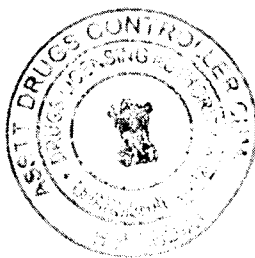
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**Annexure -A**

48.	Everolimus Tablets 5 mg	Each uncoated tablet contains: Everolimus 5 mg Excipients q.s.
49.	Everolimus Tablets 10 mg	Each uncoated tablet contains: Everolimus 10 mg Excipients q.s.
50.	Abiraterone Acetate Tablets 250 mg	Each uncoated tablet contains: Abiraterone Acetate 250 mg Excipients q.s.
51.	Capecitabine Tablets USP 500 mg	Each film coated tablet contains: Capecitabine USP 500 mg Excipients q.s. Colour : Approved Colour Used
52.	Gefitinib Tablets 250 mg	Each film coated tablet contains: Gefitinib 500 mg Excipients q.s. Colour : Approved Colour Used
53.	Imatinib Tablets 400 mg	Each film coated tablet contains: Imatinib Mesylate BP Eq. to Imatinib 400 mg Excipients q.s. Colour : Approved Colour Used
54.	Letrozole Tablets USP 2.5mg	Each film coated tablet contains: Letrozole USP 2.5 mg Excipients q.s. Colour : Approved Colour Used
55.	Dasatinib Tablets 50 mg	Each film coated tablet contains: Dasatinib 50 mg Excipients q.s. Colour : Approved Colour Used
56.	Dasatinib Tablets 70 mg	Each film coated tablet contains: Dasatinib 70 mg Excipients q.s. Colour : Approved Colour Used
57.	Dasatinib Tablets 100 mg	Each film coated tablet contains: Dasatinib 100 mg Excipients q.s. Colour : Approved Colour Used



(Ashish Raina)

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58.	Tamoxifen Tablets BP 10 mg	Each uncoated tablet contains: Tamoxifen Citrate Eq. to Tamoxifen 10 mg Excipients q.s.
59.	Tamoxifen Tablets BP 40 mg	Each uncoated tablet contains: Tamoxifen Citrate Eq. to Tamoxifen 40 mg Excipients q.s.
60.	Capecitabine Tablets USP 150 mg	Each film coated tablet contains: Capecitabine USP 150 mg Excipients q.s. Colour : Approved Colour Used
61.	Melphalan Tablets BP 2 mg	Each film coated tablet contains: Melphalan BP 2 mg Excipients q.s. Colour : Approved Colour Used
62.	Melphalan Tablets BP 4 mg	Each film coated tablet contains: Melphalan BP 4 mg Excipients q.s. Colour : Approved Colour Used
63.	Flutamide Tablets 250 mg	Each uncoated tablet contains: Flutamide USP 250 mg Excipients q.s.
64.	Lapatinib Tablets 250 mg	Each film coated tablet contains: Lapatinib Ditosylate Eq. to Lapatinib 250 mg Excipients q.s. Colour : Approved Colour Used
65.	Chlorambucil Tablets BP 2 mg	Each film coated tablet contains: Chlorambucil BP 2 mg Excipients q.s. Colour : Approved Colour Used
66.	Chlorambucil Tablets BP 5 mg	Each film coated tablet contains: Chlorambucil BP 5 mg Excipients q.s. Colour : Approved Colour Used



  
 (Ashish Raina) 26/3/21  
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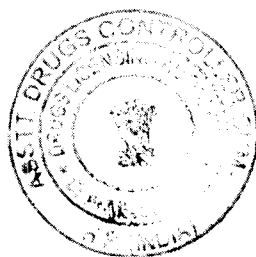
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**Annexure -A**

67.	<b>Letrozole tablets USP 2.5mg</b>	Each film coated tablet contains: Letrozole USP 2.5 mg Excipients q.s. Colour : Approved Colour Used
68.	<b>Sorafenib Tablets 200mg</b>	Each film coated tablet contains: Sorafenib Tosylate Eq. to Sorafenib 200 mg Excipients q.s. Colour : Approved Colour Used
69.	<b>Imatinib Tablets 100mg</b>	Each film coated tablet contains: Imatinib Mesylate BP Eq. to Imatinib 100 mg Excipients q.s. Colour : Approved Colour Used
70.	<b>Cyclophosphamide Tablets USP 50mg</b>	Each film coated tablet contains: Cyclophosphamide USP Eq. to anhydrous Cyclophosphamide 50 mg Excipients q.s. Colour : Approved Colour Used
71.	<b>Erlotinib Tablets 100mg</b>	Each film coated tablet contains: Erlotinib Hydrochloride Eq. to Erlotinib 100 mg Excipients q.s. Colour : Approved Colour Used
72.	<b>Erlotinib Tablets 150mg</b>	Each film coated tablet contains: Erlotinib Hydrochloride Eq. to Erlotinib 150 mg Excipients q.s. Colour : Approved Colour Used
73.	<b>Afatinib Tablets 20mg</b>	Each film coated tablet contains: Afatinib Dimaleate 29.56 mg Eq. to Afatinib 20 mg Excipients q.s. Colour : Approved Colour Used



  
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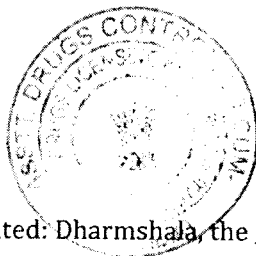
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74.	<b>Afatinib Tablets 30mg</b>	Each film coated tablet contains: Afatinib Dimaleate 44.34 mg Eq. to Afatinib 30 mg Excipients q.s. Colour : Approved Colour Used
75.	<b>Afatinib Tablets 40mg</b>	Each film coated tablet contains: Afatinib Dimaleate 59.12 mg Eq. to Afatinib 40 mg Excipients q.s. Colour : Approved Colour Used
76.	<b>Afatinib Tablets 50mg</b>	Each film coated tablet contains: Afatinib Dimaleate 73.9 mg Eq. to Afatinib 50 mg Excipients q.s. Colour : Approved Colour Used
77.	<b>Anastrozole Tablets USP 1mg</b>	Each film coated tablet contains: Anastrozole USP 1 mg Excipients q.s. Colour : Approved Colour Used
78.	<b>Letrozole Tablets USP 2.5mg</b>	Each uncoated tablet contains: Letrozole USP 2.5 mg Excipients q.s.
79.	<b>Cyclophosphamide Tablets BP 50mg</b>	Each sugar coated tablet contains: Cyclophosphamide BP Eq. to anhydrous Cyclophosphamide 50 mg Excipients q.s. Colour : Approved Colour Used
80.	<b>Pazopanib Tablets 200 mg</b>	Each film coated tablet contains: Pazopanib hydrochloride 216.7 mg Eq. to Pazopanib 200 mg Excipients q.s. Colour : Approved Colour Used
81.	<b>Pazopanib Tablets 400 mg</b>	Each film coated tablet contains: Pazopanib hydrochloride 433.4 mg Eq. to Pazopanib 400 mg Excipients q.s. Colour : Approved Colour Used



*(Signature)*  
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82.	Dasatinib Tablets 20 mg	Each film coated tablet contains: Dasatinib 20 mg Excipients q.s. Colour : Approved Colour Used
83.	Methotrexate Tablets USP 2.5 mg	Each uncoated tablet contains: Methotrexate USP 2.5 mg Excipients q.s.
84.	Temozolomide Capsule 20 mg	Each hard gelatin capsule contains: Temozolomide USP 20 mg Excipients q.s. Approved colour used in empty capsule shell
85.	Temozolomide Capsule 100 mg	Each hard gelatin capsule contains: Temozolomide USP 100 mg Excipients q.s. Approved colour used in empty capsule shell
86.	Temozolomide Capsule 250 mg	Each hard gelatin capsule contains: Temozolomide USP 250 mg Excipients q.s. Approved colour used in empty capsule shell
87.	Hydroxyurea Capsules USP 500mg	Each hard gelatin capsule contains: Hydroxyurea USP 500 mg Excipients q.s. Approved colour used in empty capsule shell
88.	Sunitinib Maleate Capsules 12.5 mg	Each hard gelatin capsule contains: Sunitinib Maleate Eq. to Sunitinib 12.5 mg Excipients q.s. Approved colour used in empty capsule shell
89.	Etoposide Capsules USP 100 mg	Each hard gelatin capsule contains: Etoposide USP 100 mg Excipients q.s. Approved colour used in empty capsule shell
90.	Aprepitant Capsules USP 80mg	Each hard gelatin capsule contains: Aprepitant USP 80 mg Excipients q.s. Approved colour used in empty capsule shell
91.	Aprepitant Capsules USP 125mg	Each hard gelatin capsule contains: Aprepitant USP 125 mg Excipients q.s. Approved colour used in empty capsule shell



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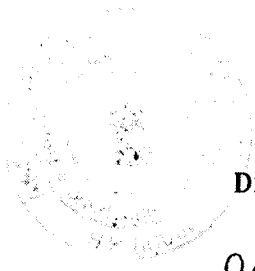
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**Annexure -A**

92.	<b>Combipack of one capsule of Aprepitant Capsules USP 125mg &amp; two capsules of Aprepitant Capsules USP 80mg</b>	Each hard gelatin capsule contains: Aprepitant USP 80 mg Excipients q.s. Approved colour used in empty capsule shell
		Each hard gelatin capsule contains: Aprepitant USP 125 mg Excipients q.s. Approved colour used in empty capsule shell
93.	<b>Imatinib Capsules 100 mg</b>	Each hard gelatin capsule contains: Imatinib Mesylate BP Eq. to Imatinib 100 mg Excipients q.s. Approved colour used in empty capsule shell
94.	<b>Imatinib Capsules 400 mg</b>	Each hard gelatin capsule contains: Imatinib Mesylate BP Eq. to Imatinib 400 mg Excipients q.s. Approved colour used in empty capsule shell
95.	<b>Sunitinib Maleate Capsules 50 mg</b>	Each hard gelatin capsule contains: Sunitinib Maleate Eq. to Sunitinib 50 mg Excipients q.s. Approved colour used in empty capsule shell
96.	<b>Hydroxyurea Capsules USP 500mg</b>	Each hard gelatin capsule contains: Hydroxyurea USP 500 mg Excipients q.s. Approved colour used in empty capsule shell
97.	<b>Nilotinib Capsules USP 150mg</b>	Each hard gelatin capsule contains: Nilotinib USP 150 mg Excipients q.s. Approved colour used in empty capsule shell
98.	<b>Temozolomide Capsules USP 100 mg</b>	Each hard gelatin capsule contains: Temozolomide USP 100 mg Excipients q.s. Approved colour used in empty capsule shell



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26/3/21  
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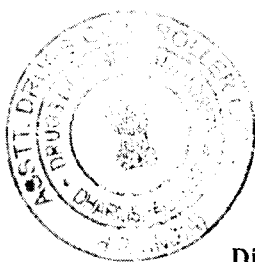
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99.	Etoposide Capsules USP 50 mg	Each hard gelatin capsule contains: Etoposide USP 50 mg Excipients q.s. Approved colour used in empty capsule shell
100.	Lenalidomide Capsules 5 mg	Each hard gelatin capsule contains: Lenalidomide 5 mg Excipients q.s. Approved colour used in empty capsule shell
101.	Lenalidomide Capsules 10 mg	Each hard gelatin capsule contains: Lenalidomide 10 mg Excipients q.s. Approved colour used in empty capsule shell
102.	Lenalidomide Capsules 25 mg	Each hard gelatin capsule contains: Lenalidomide 25 mg Excipients q.s. Approved colour used in empty capsule shell
103.	Bleomycin For Injection USP 15 IU/vial (As Lyophilized)	Each vial contains: Bleomycin Sulfate USP Eq. to Bleomycin 15 IU
104.	Pemetrexed For Injection 100 mg/vial (As Lyophilized)	Each vial contains: Pemetrexed Disodium Eq. to Pemetrexed 100 mg Excipients q.s.
105.	Pemetrexed For Injection 500 mg/vial (As Lyophilized)	Each vial contains: Pemetrexed Disodium Eq. to Pemetrexed 500 mg Excipients q.s.
106.	Mitomycin For Injection USP 2 mg/vial (As Lyophilized)	Each vial contains: Mitomycin USP 2 mg Excipients q.s.
107.	Mitomycin For Injection USP 10 mg/vial (As Lyophilized)	Each vial contains: Mitomycin USP 10 mg Excipients q.s.



*Ashish Raina*  
26/3/21  
(Ashish Raina)

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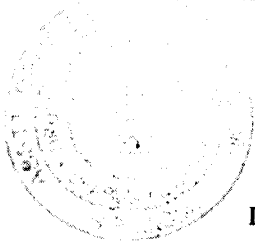
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## Annexure -A

108.	Epirubicin Hydrochloride For Injection 50 mg/vial (As Lyophilized)	Each vial contains: Epirubicin Hydrochloride BP 50 mg Lactose BP 250 mg Methylparaben BP 10 mg (As freeze dried powder)
109.	Doxorubicin Hydrochloride For Injection BP 10 mg/vial (As Lyophilized)	Each vial contains: Doxorubicin Hydrochloride BP 10 mg Excipients q.s.
110.	Doxorubicin Hydrochloride For Injection BP 50 mg/vial (As Lyophilized)	Each vial contains: Doxorubicin Hydrochloride BP 50 mg Excipients q.s.
111.	Daunorubicin Hydrochloride For Injection 20mg / Vial (As Lyophilized)	Each vial contains: Daunorubicin Hydrochloride USP Eq. to Daunorubicin 20mg Mannitol USP 100 mg
112.	Zoledronic Acid Injection 4mg/ vial (As Lyophilized)	Each vial contains: Zoledronic Acid 4 mg Excipients q.s.
113.	Bortezomib For Injection 2 mg/ vial (As Lyophilized)	Each vial contains: Bortezomib 2 mg Excipients q.s.
114.	Vincristine Injection BP 1mg/ vial (As Lyophilized)	Each vial contains: Vincristine Sulphate BP 1mg Excipients q.s.
115.	Vincristine Injection BP 2mg/ vial (As Lyophilized)	Each vial contains: Vincristine Sulphate BP 2mg Excipients q.s.
116.	Cyclophosphamide Injection BP 500mg/vial (As Lyophilized)	Each vial contains: Cyclophosphamide BP Eq. to Anhydrous Cyclophosphamide 500 mg Excipients q.s.
117.	Cyclophosphamide Injection BP 1000mg/vial (As Lyophilized)	Each vial contains: Cyclophosphamide BP Eq. to Anhydrous Cyclophosphamide 1000 mg Excipients q.s.
118.	Bendamustine Injection 100 mg/ vial (As Lyophilized)	Each vial contains: Bendamustine Hydrochloride 100 mg Excipients q.s.



*(Signature)*  
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## Annexure -A

119.	Paclitaxel ( protein -bound particles ) For Injectable Suspension 100 mg / vial (As Lyophilized)	Each vial contains: Paclitaxel BP 100 mg Human Albumin USP 900 mg
120.	Bortezomib for Injection 3.5 mg/Vial (As Lyophilized)	Each vial contains: Bortezomib 3.5 mg Excipients q.s.
121.	Bortezomib for Injection 2 mg/Vial (As Lyophilized)	Each vial contains: Bortezomib 2 mg Excipients q.s.
122.	Vincristine Sulfate for Injection USP 2mg/ vial (As Lyophilized)	Each vial contains: Vincristine Sulfate USP 2mg Mannitol USP 100 mg
123.	Ganciclovir for Injection USP 500 mg/ vial (As Lyophilized)	Each vial contains: Ganciclovir USP 500 mg Excipients q.s.
124.	Leuprolide Acetate for Injection 3.75 mg/vial (As Lyophilized)	Each vial contains: Leuprolide Acetate USP 3.75 mg Excipients q.s.
125.	Leuprolide Acetate for Injection 11.25 mg/vial (As Lyophilized)	Each vial contains: Leuprolide Acetate USP 11.25 mg Excipients q.s.
126.	Doxorubicin Hydrochloride For Injection USP 10 mg/vial (As Lyophilized)	Each vial contains: Doxorubicin Hydrochloride USP 10 mg Excipients q.s.
127.	Doxorubicin Hydrochloride For Injection USP 50 mg/vial (As Lyophilized)	Each vial contains: Doxorubicin Hydrochloride USP 50 mg Excipients q.s.
128.	Daunorubicin Hydrochloride For Injection 50mg / Vial (As Lyophilized)	Each vial contains: Daunorubicin Hydrochloride USP Eq. to Daunorubicin 50mg Excipients q.s.
129.	Ifosfamide for injection USP 1gm/ vial (As Lyophilized)	Each vial contains: Ifosfamide USP 1gm Excipients q.s.
130.	Daunorubicin Hydrochloride For Injection 20mg / Vial (As Lyophilized)	Each vial contains: Daunorubicin Hydrochloride USP Eq. to Daunorubicin 20mg Excipients q.s.

(Ashish Raina)

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## Annexure -A

131.	<b>Epirubicin Hydrochloride For Injection</b> <b>10 mg/vial</b> <b>(As Lyophilized)</b>	Each vial contains: Epirubicin Hydrochloride BP 10 mg Lactose BP 50 mg Methylparaben BP 2mg (As freeze dried powder)
132.	<b>Mitomycin For Injection USP 40 mg/vial</b> <b>(As Lyophilized)</b>	Each vial contains: Mitomycin USP 40 mg Excipients q.s.
133.	<b>Cyclophosphamide Injection USP</b> <b>500mg/vial</b> <b>(As Lyophilized)</b>	Each vial contains: Cyclophosphamide USP Eq. to Anhydrous Cyclophosphamide 500 mg Excipients q.s.
134.	<b>Oxaliplatin Injection USP 50mg/ vial</b> <b>(As Lyophilized)</b>	Each vial contains: Oxaliplatin USP 50 mg Excipients q.s.
135.	<b>Oxaliplatin Injection USP 100mg/ vial</b> <b>(As Lyophilized)</b>	Each vial contains: Oxaliplatin USP 100 mg Excipients q.s.
136.	<b>Carmustine Injection USP 100mg/ vial</b> <b>(As Lyophilized)</b>	Each vial contains: Carmustine USP 100 mg Excipients q.s.
137.	<b>Dacarbazine Injection USP 200mg/ vial</b> <b>(As Lyophilized)</b>	Each vial contains: Dacarbazine USP 200 mg Excipients q.s.
138.	<b>Azacitidine for Injection 100mg/ vial</b> <b>(As Lyophilized)</b>	Each vial contains: Azacitidine 100 mg Mannitol USP 100 mg
139.	<b>Combipack of one vial Ifosfamide for</b> <b>Injection USP 1 gm / Vial</b> <b>&amp;</b> <b>3 Vial of Mesna Injection 200 mg /2 ml</b> <i>Mesna</i>	Each vial contains: Ifosfamide USP 1gm Excipients q.s. Each ml contains: <del>Mesna</del> BP 100 mg Water for Injection BP q.s.
140.	<b>Vinblastine Sulfate For Injection BP</b> <b>5mg/vial</b> <b>(As Lyophilized)</b>	Each ml contains: Vinblastine Sulfate BP 5 mg Excipients q.s.

*(Signature)*  
26/3/21

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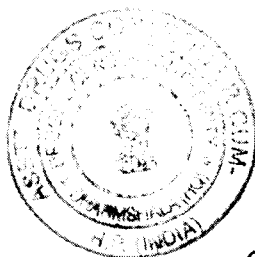
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## Annexure -A

141.	Mitomycin For Injection USP 20 mg/vial (As Lyophilized)	Each vial contains: Mitomycin USP 20 mg Excipients q.s.
142.	Gemcitabine For Injection USP 200 mg/ vial (As Lyophilized)	Each vial contains: Gemcitabine Hydrochloride USP Eq. to Gemcitabine 200 mg Excipients q.s.
143.	Gemcitabine For Injection USP 1000 mg/ vial (As Lyophilized)	Each vial contains: Gemcitabine Hydrochloride USP Eq. to Gemcitabine 1000 mg Excipients q.s.
144.	Daunorubicin Liposomal Injection 50 mg/ 25 ml	Each ml contains: Daunorubic Citrate Eq. to Daunorubicin 2 mg Water for Injection BP q.s.
145.	Nilotinib Capsules 200 mg	Each hard gelatin capsule contains: Nilotinib 200 mg Excipients q.s. Approved colour used in empty capsule shell
146.	Dactinomycin For Injection USP 500mcg / Vial (As Lyophilized)	Each vial contains: Dactinomycin USP 500 mg Mannitol USP 100 mg
147.	Cisplatin Injection BP 25mg / 25ml	Each ml contains: Cisplatin BP 1 mg Water for Injection BP q.s.
148.	Oxaliplatin Injection USP 5mg/ ml	Each ml contains: Oxaliplatin USP 5 mg Water for Injection USP q.s.
149.	Oxaliplatin Injection USP 50mg/ 10ml	Each ml contains: Oxaliplatin USP 5 mg Water for Injection USP q.s.
150.	Docetaxel Injection USP 20 mg/ ml	Each ml contains: Docetaxel Anhydrous USP 20mg Citric Acid Anhydrous USP 4 mg Polysorbate 80 USP 520 mg Dehydrated Alcohol USP 395 mg



*Ashish Raina*  
26/3/21  
(Ashish Raina)

Asstt. Drugs Controller,  
Cum- Drug Licensing Authority,  
O/o the chief Medical Officer,  
Distt. Kangra at Dharmshala H.P. INDIA

No. HFW-NZ (Drugs) 2021- 675, Dated: Dharmshala, the 26/03/2021

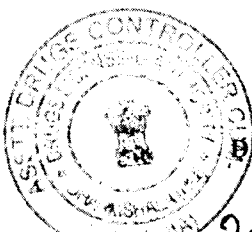
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**M/s, Kwaliti Pharmaceuticals Limited,**  
**1-A Industrial Area, Raja Ka Bagh,**  
**Tehsil Nurpur Himachal Pradesh, INDIA**

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## Annexure -A

151.	Fluorouracil Injection BP 250 mg / 5 ml	Each ml contains: Fluorouracil BP 50 mg Sodium Hydroxide BP 10 mg Water for Injection BP q.s.
152.	Decitabine For Injection 50mg / Vial (As Lyophilized)	Each vial contains : Decitabine 50 mg Excipients q.s.
153.	Fludarabine Phosphate For Injection USP 50mg / Vial (As Lyophilized)	Each vial contains : Fludarabine Phosphate USP 50 mg Mannitol BP 100 mg
154.	Mitoxantrone Injection USP 20mg / 10 ml	Each ml contains : Mitoxantrone Hydrochloride USP Eq. to Mitoxantrone 2 mg Water for Injection BP q.s.
155.	Irinotecan Hydrochloride Injection USP 100mg/ 5ml	Each ml contains: Irinotecan Hydrochloride USP 20 mg Water for Injection BP q.s.
156.	Lenalidomide Capsules 15 mg	Each hard gelatin capsule contains: Lenalidomide 15 mg Excipients q.s. Approved colour used in empty capsule shell
157.	Sunitinib Maleate Capsules 25 mg	Each hard gelatin capsule contains: Sunitinib Maleate Eq. to Sunitinib 25 mg Excipients q.s. Approved colour used in empty capsule shell
158.	Mercaptopurine Tablets BP 50mg	Each uncoated tablet contains : Mercaptopurine BP 50 mg Excipients q.s.
159.	Tamoxifen Tablets BP 20 mg	Each uncoated tablet contains: Tamoxifen Citrate BP Eq. to Tamoxifen 20 mg Excipients q.s.
160.	Vinblastine Sulfate For Injection BP 10mg / Vial (As Lyophilized)	Each vial contains : Vinblastine Sulfate BP 10 mg Excipients q.s.
161.	Vinblastine Sulfate For Injection USP 10mg / Vial (As Lyophilized)	Each vial contains : Vinblastine Sulfate USP 10 mg Excipients q.s.



(Ashish Rajna)

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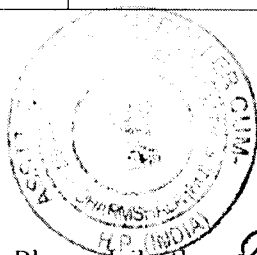
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## Annexure -A

162.	Vinblastine Sulfate Injection 10mg / 10ml	Each ml contains : Vinblastine Sulfate USP 1 mg Sodium Chloride USP 9 mg Benzyl Alcohol USP 0.9% v/v Water for Injection USP q.s.
163.	Vinblastine Sulfate 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.
164.	Vincristine sulfate for injection USP 1mg / ml	Each ml contains: Vincristine sulfate USP 1 mg Water for Injection USP q.s.
165.	Vincristine Sulfate for Injection USP 1mg/ vial (As Lyophilized)	Each vial contains: Vincristine Sulfate USP 1mg Mannitol USP 50 mg
166.	Cyclophosphamide For Injection USP 1000mg / Vial	Each vial contains : Cyclophosphamide USP Eq. to anhydrous Cyclophosphamide 1000 mg Excipients q.s.
167.	Cyclophosphamide For Injection USP 200mg / Vial	Each vial contains : Cyclophosphamide USP Eq. to anhydrous Cyclophosphamide 200 mg Excipients q.s.
168.	Fulvestrant Injection 250mg / 5ml	Each ml contains : Fulvestrant BP 50 mg Ethanol (96 per cent) BP 10% w/v
169.	Enzalutamide Capsules 40 mg	Each hard gelatin capsule contains : Enzalutamide 40 mg Excipients q.s. Approved colour used in empty capsule shell
170.	Goserelin Acetate Injection 10.8 mg / ml	Each ml contains: Goserelin Acetate Eq. to Goserelin 10.8 mg Water for Injection BP q.s.
171.	Leuprolide Acetate For Injection 22.5 mg / Vial (As Lyophilized) (3 months depot)	Each ml contains: Leuprolide Acetate USP 22.5 mg Excipients q.s.
172.	Methotrexate Injection BP 50 mg / 5ml	Each ml contains : Methotrexate BP 10mg Water for Injection BP q.s.
173.	L- Asparaginase For Injection 10000 IU/ Vial (As Lyophilized)	Each vial contains : L- Asparaginase 10000 IU



(Ashish Raina)

Asstt. Drugs Controller,

Cum- Drug Licensing Authority,

O/o the chief Medical Officer,

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