No. HFW-NZ(Drugs)2021 - 302
Health & Family Welfare Deparment H.P.
Drugs Control Administration HP,
O/o CMO's Office Complex, Dharmshala-176215, Kangra, H.P.

Date: 23/2/2021

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 ***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.

ASSTT. DRUGS CONTROLLER CUM-DRUGS LICENSING AUTHORITY DHARMSHALA (KGR) H.P. (INDIA)

23/2/21

(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) 2021-302, Dated: Dharmshala, the 23/02/2021

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: 2022.09.20 10:21:55 EEST
Reason: MoldSign Signature
Location: Moldova

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.

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

ASSTT. DRUGS CONTROLLER cum DRUGS LICENSING AUTHORITY DHARMSHALA H.P. (INDIA)

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

Issued to:

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

Free Sale Certificate
Annexure –A

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

ASSTT. DRUGS CONTROLLER CUM-DRUGS LICENSING AUTHORITY * DHARMSHALA (HQ) * H.P. (INDIA)

23/2/21

(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) 2021-302, Dated: Dharmshala, the 23/2/2021

Issued to:

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

CERTIFICATE OF PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

No. of certificate : **DCA/DML/KWL/2022/025** **VALID UPTO**: 16.02.2024

Exporting (certifying) country : **INDIA**
Importing (requesting) country : **As per Annexure**

1. Name and dosage form of product : **Leuprolide Acetate For Injection 3.75mg (As Lyophilized)**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **a) Each vial contains:**
Leuprolide Acetate USP 3.75mg
Excipients q.s.

b) **Solvent 2ml ampoule (diluent)**
Each ml contains:
Carboxymethylcellulose Sodium USP 0.625mg
Mannitol USP 50mg
Polysorbate 80 USP 5mg
Water for Injection USP q.s.

For complete qualitative composition including excipients, see attached.[4] NA

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] Yes [×] No [ ]

1.3 Is this product actually on the market in the exporting country? Yes [×] No [ ] Unknown [ ]

If the answer to 1.2 is Yes, continue with section 2A and omit section 2B
If the answer to 1.2 is No, omit section 2A continue section 2B[6]

2A

A.1 Number of product license[7] **NNZ/08/40 & BNZ/08/41**
and date of issue : 28.12.2020

A.2 Product license holder: **KWALITY PHARMACEUTICALS LTD.**
(Name and address) **1-A, Industrial Area, Raja Ka Bagh**
Teh: Nurpur, Distt: Kangra (H.P.)
PIN: 176201

A.3 Status of product license Holder[8]
a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the Manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?**[10]
Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]
Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

B.1 Applicant for certificate (name and address)

B.2 Status of application:
a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking

Not Required	Not Requested	under consideration	refused
[ ]	[ ]	[ ]	[ ]

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Once in a Year**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[15]
Yes [×] No [ ] Not applicable [ ]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]
Yes [X] No [ ] Not applicable [ ]

If no, explain:

Address of certifying authority:
State Drugs Controller,
Controlling -cum- Licensing Authority,
H.P., Baddi, Distt. Solan- 173205
01795-244288, sdc4hp@gmail.com

Name of the Authorized Person: **Mr. Navneet Marwaha**

Signature:
Stamp and date: 26-4-22

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

ANNEXURE

No. of Certificate: DCA/DML/KWL/2022/025 **VALID UPTO**: 16.02.2024

Name of the Product: **Leuprolide Acetate For Injection 3.75mg (As Lyophilized)**

List of Countries/ Institution to which the above product will be Exported / locally supplied.

1. Algeria	29. Denmark	57. Japan	85. Niger	113. Spain
2. Albania	30.Dominican Republic	58. Kazakhstan	86. Nigeria	114. Tajikistan
3. Argentina	31.Ecuador	59. Kenya	87. Netherland	115 Taiwan
4. Armenia	32.Egypt	60. Kuwait	88. Newzealand	116 Tanzania
5. Azerbaijan	33.El Salvador	61. Kyrgyzstan	89. Oman	117. Thailand
6. Afganistan	34.Estonia	62. Korea	90. Pakistan	118. Togo
7. Australia	35.Ethiopia	63. Laos	91. Panama	119. Tonga
8. Bahrain	36.Fiji	64. Latvia	92. Papua New Guinea	120. Trinidad & Tobago
9. Bangladesh	37.France	65. Lebanon	93. Paraguay	121. Tunisia
10. Belarus	38.Gabon	66. Liberia	94. Peru	122. Turkey
11. Belize	39. Ghana	67. Libya	95. Philippines	123. UAE
12. Belorussia	40. Guatemala	68. Lithuania	96. Poland	124. Uganda
13. Benin	41. Guinea	69. Malawi	97. Qatar	125. Ukraine
14. Bolivia	42. Gambia	70. Malaysia	98. Romania	126. United Kingdom
15. Brazil	43. Goorgia	71. Male	99. Russia	127. Uruguay
16. Bulgaria	44. Germany	72. Mali	100. Rwanda	128. USA
17. Bhutan	45. Haiti	73. Mauritania	101. Samoa	129. Uzbekistan
18. Burkina Faso	46. Honduras	74. Mauritius	102. Saudi Arabia	130. Venezuala
19. Cambodia	47 Hungary	75. Mexico	103. Senegal	131. Vietnam
20. Cameroon	48. Indonesia	76. Moldova	104. Sierra Leone	132. Yemen
21. Chile	49. Iran	77. Mongolia	105. Slovakia	133. Zaire
22. China	50. Iraq	78. Morocco	106. Slovenia	134. Zambia
23. Columbia	51. Israel	79. Myanmar	107. South Africa	135. Zimbabwe
24. Congo	52. Ivory Coast	80. Mozambique	108. South Korea	136. South Sudan
25. Costa Rica	53. Ireland	81. Namibia	108. Sri Lanka	137.Democratic Republic Of Laos
26. Cuba	54. Italy	82. Nepal	110. Sudan	138. Brunei
27. Czech Republic	55. Jamaica	83. New Zealand	111. Suriname	139.Iceland
28. Curacao	56. Jordan	84. India	112. Syria	140. Turkmenistan

Licensing Authority cum Drug Controller * Himachal Pradesh *

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

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

To,

M/s Kwality 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.

20/4/2021

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

Encl; GMP certificates & 402 COPPS

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: 20/4/2021

On the basis of the Joint Inspection made by Drugs Inspectors of CDSCO (Sub Zone Baddi) and Drugs Inspectors of State on 18th & 19th 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 Kwality Pharmaceuticals Limited, Situated at 6th 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 :

Asstt. Commissioner (Drugs) ☆ Food & Drugs Administration, Punjab ☆ सत्यमेव जयते

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.

Asstt. Commissioner (Drugs) Food & Drugs Administration, Punjab सत्यमेव जयते

Assistant Commissioner (Drugs)-cum-Licensing Authority, FDA Punjab, Near Civil Hospital Kharar-140301, District Sahibzada Ajit Singh Nagar.
20/4/2021

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

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