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/2024/018** **VALID UPTO**: 15.02.2025

21 MAR 2024

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

1. Name and dosage form of product : **Paclitaxel (Protein-Bound Particles) For Injectable Suspension 100mg/vial**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each vial contains:**
Paclitaxel USP 100mg
Human Albumin USP 900mg

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 :

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:

Licensing Authority cum Controller ★ Himachal Pradesh ★

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

Name of the Authorized Person: Dr. Manish Kapoor

Signature:
Stamp and date:

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

21 MAR 2024

ANNEXURE

No. of certificate : **DCA/DML/KWL/2024/018**

VALID UPTO: 15.02.2025

21 MAR 2024

Name of the Product: **Paclitaxel (Protein-Bound Particles) For Injectable Suspension 100mg/vial**

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 Controller ★ Himachal Pradesh ★ सत्यमेव जयते

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

Name of the Authorized Person: Dr. Manish Kapoor

Signature:
Stamp and date:

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

21 MAR 2024

Bulgarian Drug Agency

CERTIFICATE NUMBER: ***BG/GMP/2023/240***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Bulgaria confirms the following:
The manufacturer: ***Kwality Pharmaceuticals Limited***
Site address: ***I A Industrial Area, Raja Ka Bagh, Tehsil Nurpur Distt, Kangra (H.P.), 176201***
OMS Organisation Id. / OMS Location Id.: ***ORG-100048403*** / ***LOC-100080161***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-04-21***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: (powder for injection)(en)
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: oral powder in sachet(en) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: oral powder in sachet(en) 1.5.1.13 Tablets Special Requirements 7 Other: non-coated and film-coated tablets(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

Inspection covers manufacturing and testing of medicinal products in Cytotoxic Block and Cephalosporin Block: Cytotoxic Block: Sterile medicinal products; Aseptically prepared (processing operations for the following Dosage forms): Small volume liquids (vial) and Lyophilized Injection. Non-sterile products; Non-sterile products (processing operations for the following Dosage forms): Capsules, hard shell; Tablets: Tablets/Coated tablets. Cephalosporin Block: Sterile medicinal products; Aseptically prepared (processing operations for the following Dosage forms): Small volume Aseptic powders for injection. Non-sterile products; Non-sterile products (processing operations for the following Dosage forms): Capsules, hard shell; Other Solid dosage form - powder for oral suspension in sachets (Oral Dry Syrups); Tablets/Coated tablets. Activities pointed out in p.1.1.1.6, p.1.2.1.8 and p.1.5.1.8 refer only to manufacture of cephalosporin block. It has been distant inspection

2023-06-21

Name and signature of the authorised person of the Competent Authority of Bulgaria

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Confidential
Bulgarian Drug Agency
Tel:***Confidential***
Fax:***Confidential***