

CERTIFICATE OF PHARMACEUTICAL PRODUCT¹

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

No. of certificate : DCA/DML/KWL/2024/038

VALID UPTO: 15.02.2025

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

15 APR 2024

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

1.1 Active ingredient(s)² and amount(s) per unit dose³ : Each vial contains:
Leuprorelin BP (as acetate) 3.75 mg
Excipients 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 2B⁶

2A

A.1 Number of product license⁷ 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 Holder⁸
a b c

A3.1 For categories b and c the name and address of the
Manufacturer producing the dosage
form are⁹ : 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 holder¹² : 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 are⁹

B.3 Why is marketing authorization lacking

Not Not under refused
Required Requested consideration

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 applicable¹⁴

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 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: 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

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ANNEXURE

No. of Certificate: DCA/DML/KWL/2024/038

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Name of the Product: Leuprolide Acetate Depot for Injection 3.75mg (As Lyophilized)

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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. Georgia	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



Mamukh
 State Drugs Controller
 Controlling cum Licensing Authority
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