# 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.

Digitally signed by Moraru Grigore
Date: 2023.08.28 08:18:14 EEST
Reason: MoldSign Signature
Location: Moldova

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

Licensing Authority cum Drug Controller Himachal Pradesh

**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
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