

**CERTIFICATE OF PHARMACEUTICAL PRODUCT<sup>1</sup>**

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

No. of the certificate : HFW-NZ(Drugs)92/19/2023-142 VALID UPTO: 20/02/2026

Exporting (certifying) country : INDIA

Importing (requesting) country : As per Annexure

1. Name and dosage form of product : Fludarabine Phosphate for Injection USP 50mg/vial (As Lyophilized)

1.1 Active ingredient(s)<sup>2</sup> and amount(s) per unit Dose<sup>3</sup> Each vial contains  
Fludarabine Phosphate USP.....50mg  
Excipients.....q.s.

For complete qualitative composition including Excipients<sup>4</sup> NA

1.2 Is this product licensed to be placed on the market for use in exporting country?<sup>5</sup> 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 and continue with section 2B<sup>6</sup>

<p>2A.</p> <p>A.1 Number of product license<sup>7</sup> <b>NNZ/2019/144 &amp; BNZ/2019/145</b> and date of issue: <b>08/01/2021</b></p> <p>A.2 Product-license holder: <b>M/s Biozenta Lifescience Pvt. Ltd.</b> (name &amp; address) <b>Khasra No. 59, 60 &amp; 61, Bela Bathri, Tehsil Haroli, Distt. Una Himachal Pradesh 174301 India</b></p> <p>A.3 Status of product-license holder<sup>8</sup> a <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/></p> <p>A.3.1 For categories b &amp; c the name and address of the manufacturer producing the dosage form is<sup>9</sup>: <b>Not Applicable</b></p> <p>A.4 Is summary basis of approval appended?<sup>10</sup> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input checked="" type="checkbox"/></p> <p>A.5 Is the attached, officially approved product information complete and consonant with the license?<sup>11</sup> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> Not provided <input checked="" type="checkbox"/></p> <p>A.6 Applicant for certificate, if Different from the license Holder (name and address)<sup>12</sup> <b>Not Applicable</b></p>	<p>2B</p> <p>B.1 Applicant for certificate (name &amp; address):</p> <p>B.2 Status of Applicant a <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/> d <input type="checkbox"/></p> <p>B.2.1 For categories b and c the name and address of the manufacturer producing the dosage forms are<sup>9</sup></p> <p>B.3 Why is marketing authorization lacking? <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <b>Not required Not requested Under consideration Refused</b></p> <p>B.4 Remarks<sup>13</sup></p>
--	--

3. Does the certifying authority arrange for Periodic inspection of Manufacturing Plant in which the dosage form is produced?  
**Yes** ☒ **No** ☐ **Not applicable**<sup>14</sup> ☐

If no or not applicable proceed to question 4

3.1 Periodicity of routine inspections (Years) : **Yearly**

3.2 Has the manufacturer of this type of dosage form been inspected **Yes** ☒ **No** ☐

3.3 Do the facilities and operations conform to GMP as recommended by the World Health organization?<sup>15</sup>  
**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<sup>16</sup>  
**Yes** ☐ **No** ☐ **Not Applicable** ☒

Address of Certifying authority:

**State Drugs Controller,  
Licensing Authority-cum Controlling Authority  
Baddi – 173205, Distt. – Solan (H.P.) INDIA  
Tel. No. 01795 244288  
Fax. No. 01795 244288**

Name of the Authorised Person: **Navneet Marwaha**

Signature:

Stamp and date:



**(NAVNEET MARWAHA)**  
State Drugs Controller,  
Licensing Authority-cum Controlling Authority  
Baddi Distt. Solan (H.P.) INDIA  
Tel. No. 01795 244288  
Fax. No. 01795 244288  
09 MAR 2023

## ANNEXURE I

No. of the certificate: HFW-NZ(Drugs)92/19/2023-142

VALID UPTO: 20/02/2026

**Name of the Product: Fludarabine Phosphate for Injection USP 50mg/vial (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. Nicaragua	112. Syria	140. Turkmenistan



  
 (NAVNEET MARWAHA)  
 State Drugs Controller  
 Controlling cum Licensing Authority  
 Gaddi Dist. Solan (H.P.)-176025  
 Tel-244288, Fax-244288, Email-244288@nic.com  
**09 MAR 2023**