GOVERNMENT OF HIMACHAL PRADESH
DRUGS CONTROL ADMINISTRATION

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 the certificate: HFW-NZ(Drugs)/2019/2021-12	**Valid up to: 09.02.2023**
Exporting (certifying) country	**INDIA**
Importing (requesting) country	**Annexure I**
1. Name and dosage form of product	Vincristine Sulphate Injection USP 1.0mg/ml
1.1 Active ingredient(s)[2] and amount(s) per unit Dose[3] For complete qualitative composition including Excipients[4]	Each ml contains Vincristine Sulphate USP 1.0 mg Water for Injection BP q.s.
1.2 Is this product licensed to be placed on the market for use in exporting country ?[5] **:YES** Yes / No (Key in as appropriate)	
1.3 Is this product actually on the market in the exporting country? **:YES** Yes/ No / Unknown *(Key in as appropriate)* 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[6]	
2A.1 Number of product license[7] and date of issue:	**NNZ/2019/144 in Form 25 &BNZ/2019/145 in Form 28 Dated:11.08.2020**
2A.2 Product-license holder (name & address):	M/s Biozenta Lifescience Pvt. Ltd. Khasra No. 59, 60 & 61, Bela Bathri, Haroli, Distt. Una Himachal Pradesh 174301 India
2A.3 Status of product-license holder [8] **a / b / c** *(key in as appropriate as defined in note 8)*	**a** ☑ **b** ☐ **c** ☐
2A.3.1For categories b & c the name and address of the manufacturer producing the dosage form is[9]	**NOT APPLICABLE**
2A.4ls summary basis of approval appended? [10] **Yes / No** *(key in as appropriate as defined in note)*	**NO**
2A.5Is the attached, officially approved product information complete and consonant with the license? [11] **Yes/No/ Not provided** *(Key in as appropriate)*	**NOT PROVIDED**
2A.6Applicant for certificate, if Different from the license Holder (name and address) [12]	NA
2B.1 Applicant for certificate (name & address):	
2B.2 Status of Applicant **a/b/c***(key in as appropriate)*	
2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage forms are[9]	
2B.3 Why is marketing authorization lacking? **Not required / Not requested Under consideration / Refused** *(key in as appropriate)*	
2B.4 Remarks[13]	
3. Does the certifying authority arrange for Periodic inspection of Manufacturing Plant in which the dosage form is produced? [14] **Yes / No/ Not applicable** *(Key in as appropriate* If no or not applicable proceed to question 4	**YES**
3.1 Periodicity of routine inspections (Years)	**ONCE IN A YEAR**
3.2 Has the manufacturer of this type of dosage form been inspected **Yes / No/ Not applicable** *(Key in as appropriate)*	**YES**
3.3 Do the facilities and operations conform to GMP as recommended by the World Health organization? [15] **Yes /No/ Not applicable** *(Key in as appropriate)*	**YES**
4.Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16] **Yes/ No***(Key in as appropriate)*	**NOT APPLICABLE**
5. Address of Certifying authority:	**State Drug Controller** **Controlling Cum Licensing Authority** **Baddi, Distt. Solan (H.P) 173205** **01795-244288, Email: sdc4hp@gmail.com**
6. Telephone Number	**Tel.No.01795-244288**
7. Fax Number	**-**
8. Name of authorized person:	**Navneet Marwaha**
9. Signature	
10. Stamp and Date	ALL PRODUCT APPROVALS AS ABOVE ARE VALID SUBJECT TO ... COMPLIANCE OF ALL KINDS OF DIRECTIVES/GUIDELINES BY ... MANUFACTURER WHICH ARE ISSUED BY DCGI/CDSCO OFFICE ... TIME TO TIME & COMPLIANCE OF DRUGS & COSMETICS ACT 19... RULES 1945 MADE THERE UNDER, INCLUDING AMENDMENTS MADE FROM TIME TO TIME 19/5/2020 Asstt. Drugs Controller Cum Drug Licensing Authority O/o Chief Medical Officer Distt. Kangra at Dharamshala (H.P.) E-mail: ashishraina25gmail.com Tel. No. 01892-224874

ANNEXURE I

No. of the certificate : HFW-NZ(Drugs)/2019/2021-12 **Valid up to: 09.02.2023**
Name of the Product : Vincristine Sulphate Injection USP 1.0mg/ml

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.EI 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	109. 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.lceland
28.Curacao	56.Jordan	84. Nicaragua	112. Syria	140. Turkmenistan

ALL PRODUCT APPROVALS AS ABOVE ARE VALID SUBJECT TO [illegible] COMPLIANCE OF ALL KINDS OF DIRECTIVES/GUIDELINES BY [illegible] MANUFACTURER WHICH ARE ISSUED BY DCGI/CDSCO OFFICE [illegible] TIME TO TIME & COMPLIANCE OF DRUGS & COSMETICS ACT 19[illegible] RULES 1945 MADE THERE UNDER, INCLUDING AMENDMENTS MA[illegible] FROM TIME TO TIME

19/5/2020
Asstt. Drugs Controller Cum
Drug Licensing Authority
O/o Chief Medical Officer
Distt. Kangra at Dharamshala (H.P.)
E-mail: ashishraina25gmail.com
Tel. No. 01892-224874

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