Biozenta	Biozenta Lifescience Pvt. Ltd. Khasra No. 59, 60 & 61 Bela Bathri, Haroli, Una, Himachal Pradesh 174301 India

CERTIFICATE OF ANALYSIS FOR FINISH PRODUCT

(The Drugs & Cosmetics Act 1940 and the rules there under form 39)

Product Name	CLADBINDN 10		
Generic Name	Cladribine Injection USP 10mg/10ml	Page No.	1 of 2
Batch No.	OI20029	**AR No.**	IF20080031D
Reference	USP	**Product Code**	CD/001
Mfg Date	08.2020	**Batch Size**	50 Nos.
Exp. Date	07.2022	**Sample Qty**	5 Nos.
Date of Sampling	15.08.2020	**Date of Release**	29.08.2020

Sr. No.	Test	Specification	Results
1.	Description	A clear colourless solution filled in 10 ml clear glass vial USP Type I, stoppered with 20mm slotted bromo butyl rubber plug and sealed with 20mm Aluminium flip off seal having blue colour.	A clear colourless solution filled in 10 ml clear glass vial USP Type I, stoppered with 20mm slotted bromo butyl rubber plug and sealed with 20mm Aluminium flip off seal having blue colour.
2.	Identification		
A)	By UV	The UV Absorption spectra of the test solution and standard solution should exhibit maxima and minima at the same wavelength.	The UV Absorption spectra of the test solution and standard solution should exhibit maxima and minima at the same wavelength.
B)	By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
3.	pH	5.5 to 8.0	6.35
4.	Average Fill Volume	Not Less Than 10.0 ml	10.02 ml
5.	Osmolality and Osmolarity	250 – 370 mOsmol/kg	280 mOsmol/kg
6.	Particulate Matter Visible particulate matter Sub Visible particulate matter	Free from visible 1. Not more than 6000 average number of particles should be greater than or equal to 10µm.	Digitally signed by Guțan Ghenadie Date: 2022.07.21 09:39:00 EEST Reason: MoldSign Signature Location: Moldova 28

	Analyzed By	Checked By	Approved By
Name	Pooja Gupta	Parveen Kumar	Surinder Kumar
Designation	**Executive QC**	**Sr. Executive QC**	**Astt. Manager**
Sign			
Date	29.08.2020	29.08.2020	29.08.2020

Biozenta Lifescience Pvt. Ltd. Quality Control

Format No.: QC024/F02-00

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		2. Not more than 600 average number of particles should be greater than or equal to 25µm.		03
7.	Bacterial Endotoxin Test	NMT 55 USP Endotoxin Units/mg of Cladribine.		LT 55 USP Endotoxin Units/mg of Cladribine.
8.	Sterility	Should be Sterile		Sterile
9.	**Assay**	**Claim**	**Limit**	**Obtained**
Each ml contains Cladribine USP		1.0 mg	0.90 mg – 1.1 mg (90.0% – 110.0%)	1.011 mg (101.10%)

Remarks: In the opinion of the undersigned the sample complies / does not comply with the IP/ BP/USP/In-House Specifications.

	Analyzed By	**Checked By**	**Approved By**
Name	Pooja Gupta	Parveen Kumar	Surinder Kumar
Designation	**Executive QC**	**Sr. Executive QC**	**Astt. Manager**
Sign			
Date	29.08.2020	29.08.2020	29.08.2020

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