



# VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour-173030. HP

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : Nicol 1g Chloramphenicol Sodium Succinate Injection IP	
<b>Batch No.</b> : D24H-05A	<b>Mfg. Date</b> : 08/2024
<b>Batch Size</b> : 2918 Vials	<b>Exp. Date</b> : 07/2026
<b>Sample Qty.</b> : 50 Vials	<b>Analytical Report No.:</b> XFP20240062
<b>Date of Receiving</b> : 25/09/2024	<b>Date of Completion</b> : 10/10/2024
<b>Mfg. License No.</b> : N-MB/18/201	

S. No.	Tests	Specifications	Observations
1.	Description	A white or yellowish white powder, hygroscopic, filled in transparent glass vial.	A white, hygroscopic powder, filled in transparent glass vial.
2.	Identification		
	Test A By TLC	The two principal spots in the chromatogram obtained with the test solution are similar in position and size to those in the chromatogram obtained with reference solution (a) and their position are different from that of the principal spot in the chromatogram obtained with reference solution (b).	Complies
	Test B BY Chemically	No red colour is produced.	Complies
	Test C By Chemically	It yield a curdy white precipitate.	Complies
	Test D By chemically	Gives reaction of sodium salt.	Complies
3.	Uniformity of weight	$\pm 10.0$ % of the average fill weight	Complies
4.	Average fill Weight	1414.90 mg $\pm 2$ %	1418.29 mg
5.	pH	6.40 to 7.0 determined in 25.0% w/v solution.	6.93
6.	Free chloramphenicol (By TLC)	Any spot corresponding to chloramphenicol obtained with the test solution in not more intense than the spot in the chromatogram obtained with the reference solution.	Complies
7.	Specific optical rotation	+5.0 <sup>o</sup> to +8.0 <sup>o</sup>	+7.50 <sup>o</sup>
8.	Clarity of solution	The solid dissolves completely leaving no visible residue as undissolved matter.	Complies
9.	Particulate Matter	The solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies
10.	Sterility	Should be Sterile	Sterile
11.	Water	NMT 2.0 % (Determine on 0.3 g)	1.29 %
12.	Bacterial Endotoxins	NMT 0.2 EU/mg of chloramphenicol.	Less than 0.2 EU/mg of chloramphenicol.
13.	Assay : Each vial contains:-		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Chloramphenicol sodium succinate (Sterile) IP Eq. to Chloramphenicol	1000.0 mg	1030.01 mg	103.01 %	90.0% to 110%

**Remarks:** In the opinion of the undersigned the sample submitted ~~complies/does not comply~~ with the prescribed standard/~~not standard of quality~~, as according to IP & IHS with respect to the above test only.

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager/ In-charge
Signature:- Date:- 10/10/2024	Signature:- Date:- 10/10/2024	Signature:- Date:- 10/10/2024

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