AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title	:	Certificate of Analysis Finished Product

Product Name	**NICOL** Injection	**A.R. No.**	ARN/FP/25/062
Generic Name	Chloramphenicol Sodium Succinate for Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	ARN2576A	**Sampled by**	Rakesh
Batch Size	4,920 Vials	**Sampled on**	02/12/2025
Mfg. Date	11/2025	**Date of Testing**	03/12/2025
Exp. Date	10/2027	**Date of Release**	17/12/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification (By TLC)	**A**. 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 positions are different from that of .the principal spot in the chromatogram obtained with reference solution (b).	Complies
	(By Chemically)	**B**. Dissolve 10 mg in 2 ml of ethanol (95 per cent) add 4.5 mi of 1M sulphuric acid and 50 mg of zinc powder, allow to stand for 10 minutes and decant the supernatant liquid or filter, if necessary. Cool the resulting solution in ice and add 0.5 ml of sodium nitrite solution and, after 2 minutes, 1 g of urea followed by .1 ml of 2-naphthol Solution and 2 ml of 10 M Sodium hydroxide-, a red colour develops. Repeat the test omitting the zinc powder; no red colour is produced	Complies
	(By Chemically)	**C.** To 5 ml of a 0.1 per cent w/v solution add a few drops of silver nitrate solution', no precipitate is produced. Heat 50 mg with 2 ml of ethanolic potassium hydroxide solution on a water-bath for 15 minutes, add 50 mg of decolorising charcoal, shake and filter. The filtrate when treated with silver nitrate solution, yields a curdy precipitate which is insoluble in nitric acid but soluble, after being well washed with water, in dilute ammonia solution from which it is reprecipitated on addition of nitric acid.	Complies

Analysis by	Checked by	Approved by
NAME: SACHIN KUMAR	NAME: SUFIYAN ANSARI	NAME:MRS. SWATI DHAWAN

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	(By Chemically)	**D.** A 5 per cent w/v solution gives the reactions of sodium salts	Complies
3.	Uniformity of Weight	Fill weight ±10%	-2.88% & +1.25%
4.	Average fill	Average weight±2%	1360.4mg
5.	pH	6.4 - 7.0	6.67
6.	Water	NMT-2.0%	1.72%
7.	Specific Rotation	Between $+5.0^0$ and $+8.0^0$	5.97^0
8.	Free Chloramphenicol	Any spot corresponding to chloramphenicol in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the Reference solution.	Complies
9.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm (b.) Visual	NMT-6000/vial NMT-600/vial The solution is free from particles of foreign matter particles that can be observed on visual inspection.	91/vial 1/vial Complies
10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT-0.2 EU/mg of Chloramphenicol	Less than-0.2 EU/mg of Chloramphenicol.
12.	Assay: Each glass vial Contains :		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Chloramphenicol sodium succinate (Sterile) IP Eq. to Chloramphenicol	1000 mg	951.13 mg	95.11%	90.0 to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is ~~not of~~ the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/~~not~~ complies as per IP/~~BP/USP/IHS~~.

Analysis by	Checked by	Approved by
NAME: SACHIN KUMAR	NAME: SUFIYAN ANSARI	NAME:MRS. SWATI DHAWAN