



# 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/25/091
Generic Name	Chloramphenicol Sodium Succinate for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARN25104A	Sampled by	Anuj Verma
Batch Size	6,900 Vials	Sampled on	31/01/2026
Mfg. Date	01/2026	Date of Testing	31/01/2026
Exp. Date	12/2027	Date of Release	17/02/2026

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 ml 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

NAME: RAMANJEET SINGH

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN

**Title**

**Certificate of Analysis Finished Product**

<b>Product Name</b>	NICOL Injection	<b>A.R. No.</b>	ARN/FP/25/091
<b>Generic Name</b>	Chloramphenicol Sodium Succinate for Injection IP 1gm	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	ARN25104A	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	6,900 Vials	<b>Sampled on</b>	31/01/2026
<b>Mfg. Date</b>	01/2026	<b>Date of Testing</b>	31/01/2026
<b>Exp. Date</b>	12/2027	<b>Date of Release</b>	17/02/2026

	(By Chemically)	<b>D.</b> A 5 per cent w/v solution gives the reactions of sodium salts	Complies		
3.	Uniformity of Weight	Fill weight $\pm 10\%$	-2.98% & +1.83%		
4.	Average fill	Average weight $\pm 2\%$	1376.1mg		
5.	pH	6.4 - 7.0	6.61		
6.	Water	NMT-2.0%	1.32%		
7.	Specific Rotation	Between $+5.0^0$ and $+8.0^0$	$5.26^0$		
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 $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (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.	156/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 :				
<b>Ingredients</b>		<b>Labeled Claim</b>	<b>Found</b>	<b>% of labeled amount</b>	<b>Limits % of labeled amount</b>
Chloramphenicol sodium succinate (Sterile) IP Eq. to Chloramphenicol		1000 mg	1046.46 mg	104.65%	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/HS.

<b>Analysis by</b> NAME: RAMANJEET SINGH	<b>Checked by</b> NAME: SUFIYAN ANSARI	<b>Approved by</b> NAME: MRS. SWATI DHAWAN
---	---	---