

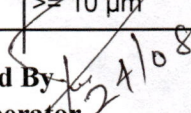
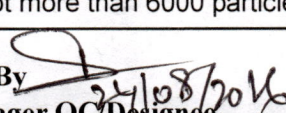
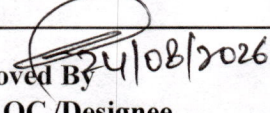
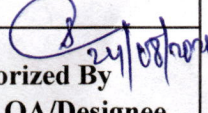


Finished Product Certificate of Analysis

Generic Name	Chloramphenicol Sodium Succinate Injection IP 1gm	Analytical Report No.	KPL1/QC/AR/FP/2026/3317
Product Name	NICOL 1G INJECTION	Reference Pharmacopoeia	IP
Batch No.	GP866	Batch Size	14165 VIALS
Mfg. Date	June 2026	Exp. Date	May 2028
Sample Received on	15/07/2026	Specification No	KPL1/QC/SLS-11680
Analysis Initiated on	16/07/2026	Date of Release	24/08/2026

Analytical Data

Packing Presentation: CLEAR GLASS VIAL SEALED WITH BLUE COLORED FLIP OFF HAVING PAPER LABEL.

S.No.	Tests	Specifications	Observations
1	Description	Before reconstitution: Yellowish white colored powder filled in clear glass vial sealed with blue colored flip off having paper label. After reconstitution: Light yellow color solution after reconstitution. Reconstitution time: Not more than 1 minute.	Yellowish white colored powder filled in clear glass vial sealed with blue colored flip off having paper label Light yellow colored solution Less than 1 minute.
2	Identification.		
	A Thin-layer chromatography	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).	Identified
	B Color test	Red colour is produced.	Identified
	C Chemical test	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.	Identified
	D Sodium test	A dense ppt is produced.	Identified
3	Average fill weight	1.412 mg $\pm$ 10 percent	1.4195 mg
4	Uniformity of fill weight	$\pm$ 10 percent of average fill weight	It lies between 1.2776 mg - 1.5615 mg
5	pH	Between 6.4 to 7.0	6.72
6	Specific optical rotation	5.0° to + 8.0°	6.04°
7	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
8	Water	Not more than 2.0 percent	1.9%
9	Bacterial endotoxins	Not more than 0.2 Endotoxin Unit per mg of chloramphenicol.	Less than 0.2 Endotoxin Unit per mg of chloramphenicol.
10	Particulate matter test		
	A $\geq 10 \mu\text{m}$	Not more than 6000 particles / container	85
Prepared By  24/08/2026 Data Operator Reviewed By  24/08/2026 Asst. Manager QC/Designee Approved By  24/08/2026 Head QC/Designee Authorized By  24/08/2026 Head QA/Designee			



Finished Product Certificate of Analysis

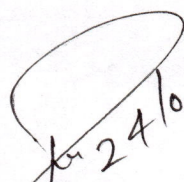
Generic Name	Chloramphenicol Sodium Succinate Injection IP 1gm	Analytical Report No.	KPL1/QC/AR/FP/2026/3317
Product Name	NICOL 1G INJECTION	Reference Pharmacopoeia	IP
Batch No.	GP866	Batch Size	14165 VIALS
Mfg. Date	June 2026	Exp. Date	May 2028
Sample Received on	15/07/2026	Specification No	KPL1/QC/SLS-11680
Analysis Initiated on	16/07/2026	Date of Release	24/08/2026

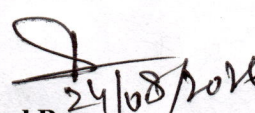
Analytical Data

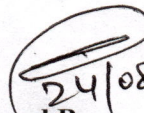
Packing Presentation: CLEAR GLASS VIAL SEALED WITH BLUE COLORED FLIP OFF HAVING PAPER LABEL.

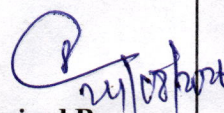
S.No.	Tests	Specifications			Observations
	B $\geq 25 \mu\text{m}$	Not more than 600 particles / container			7
11	Sterility test	Should be sterile			It is Sterile
12	Visible particle test for injection	Shall be free from visible particle			No visible particle observed
13	Assay	Limit	Claim	Result	%age
	Each vial contains: Chloramphenicol Sodium Succinate IP (Sterile) Eq. to Chloramphenicol	90.0% - 110.0%	1000 mg	1018.3 mg	101.8%

Conclusion : The above product complies with above specifications and meets the standard quality as per IP


Prepared By
Data Operator


Reviewed By
Asst. Manager QC/Designee


Approved By
Head QC/Designee


Authorized By
Head QA/Designee