

Title : Certificate of Analysis Finished Product

Product Name	Cortican Injection	A.R. No.	ARN/FP/25/033
Generic Name	Hydrocortisone Sodium Succinate Injection IP 100mg	Sampled qty.	45 Vials
Batch No.	ARN2541B	Sampled by	Aakash
Batch Size	50,000 Vials	Sampled on	08/10/2025
Mfg. Date	10/2025	Date of Testing	09/10/2025
Exp. Date	09/2027	Date of Release	24/10/2025

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 I.R	A. Determine by infrared absorption spectrophotometry compare the spectrum with that obtained with the reference spectrum of hydrocortisone sodium succinate IPRS or with the reference spectrum of hydrocortisone sodium succinate.	Complies
	By TLC	B. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with working standard solution (a).	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-5.33% & +5.56%
4.	Average weight	Informative $\pm 2\%$.	142.39 mg
5.	pH	6.5 to 8.0	7.35
6.	Related Substances, (By HPLC)		
	Any peak corresponding to Hydrocortisone	NMT 7.0%	0.54%
	Any other secondary peak	NMT 2.0%	0.12%
7.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT 6000/vial NMT 600/vial	3525/vial 8/vial
	(B.) Visual Particle	The reconstituted solution is free from particles of foreign matter particles that can be seen with naked eye.	Complies
8.	Sterility	No microbial growth should be observed.	Complies
9.	Bacterial Endotoxins	NMT 1.25 EU/mg of Hydrocortisone.	Less than 1.25 EU/mg of Hydrocortisone.

Analysis by 24/10/2025
NAME: NIKHIL SHARMA

Checked by 24/10/25
NAME: SUFIYAN ANSARI

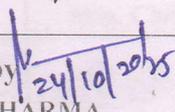
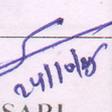
Approved by 24/10/25
NAME: MRS. SWATI DHAWAN

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10.	Assay: (By UV) Each glass vial contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Hydrocortisone Sodium Succinate (Sterile) Eq. to Hydrocortisone	IP	100 mg	101.04 mg	101.04%	95.0 to 105.0%

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~~.

Analysis by  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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