

Title		: Certificate of Analysis Finished Product	
Product Name	CORTICAN Injection	A.R. No.	ARN/FP/26/010
Generic Name	Hydrocortisone Sodium Succinate Injection IP 100mg	Sampled qty.	45 Vials
Batch No.	ARN2601A	Sampled by	Rakesh
Batch Size	20,000 Vials	Sampled on	07/05/2026
Mfg. Date	04/2026	Date of Testing	08/05/2026
Exp. Date	03/2028	Date of Release	23/05/2026

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 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 $\pm 10\%$	-5.17% & +4.91%
4.	Average weight	Informative $\pm 2\%$ .	132.9 mg
5.	pH	6.5 to 8.0	7.74
6.	Related Substances (By HPLC)		
	Any peak corresponding to Hydrocortisone	NMT 7.0%	0.982%
	Any other secondary peak	NMT 2.0%	1.805%
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	1,055/vial 6/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 <u>23/05/2026</u> NAME: NIKHIL SHARMA	Checked by <u>23/05/2026</u> NAME: SUFIYAN ANSARI	Approved by <u>23/05/2026</u> NAME: MRS. SWATIDHAWAN
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Code

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10.	Assay: (By UV) 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>
Hydrocortisone Sodium Succinate (Sterile) IP Eq. to Hydrocortisone		100 mg	99.6447 mg	99.64 %	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/IHS.

<b>Analysis by</b> NAME: NIKHIL SHARMA	<b>Checked by</b> NAME: SUFIYAN ANSARI	<b>Approved by</b> NAME: MRS. SWATI DHAWAN
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