



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

## Title : Certificate of Analysis Finished Product

<b>Product Name</b>	CORTICAN Injection	<b>A.R. No.</b>	ARN/FP/25/086
<b>Generic Name</b>	Hydrocortisone Sodium Succinate Injection IP	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	ARN25105A	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	50,400 Vials	<b>Sampled on</b>	19/01/2026
<b>Mfg. Date</b>	01/2026	<b>Date of Testing</b>	20/01/2026
<b>Exp. Date</b>	12/2027	<b>Date of Release</b>	03/02/2026

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 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 $\pm 10\%$	-1.55% & +2.62%
4.	Average weight	Informative $\pm 2\%$ .	136.7 mg
5.	pH	6.5 to 8.0	7.66
6.	Related Substances (By HPLC)		
	Any peak corresponding to Hydrocortisone	NMT 7.0%	1.23%
	Any other secondary peak	NMT 2.0%	0.83%
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	587/vial 5/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.

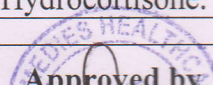
Analysis by

*[Signature]*

Checked by

*[Signature]*

Approved by





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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) IP Eq. to Hydrocortisone		100 mg	99.2408 mg	99.24 %	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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