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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)


Title


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Certificate of Analysis Finished Product

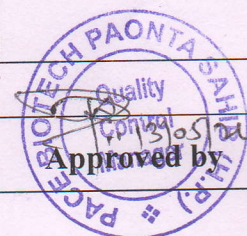
Product Name	Cortican Injection	A.R. No.	NB/FP/24/028
Generic Name	Hydrocortisone Sodium Succinate Injection IP 100mg	Sampled qty.	45 Vials
Batch No.	N23443D	Sampled by	Aakash
Batch Size	25,000 Vials	Sampled on	27/04/2024
06/10/2023	03/2024	Date of Testing	27/04/2024
Exp. Date	02/2026	Date of Release	13/05/2024

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. By TLC	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. B. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with working standard solution.	Complies Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-3.29% & +3.72%
4.	Average weight	Informative.	139.7 mg
5.	pH	6.5 to 8.0	7.66
6.	Related Substances	In the chromatogram obtained with the test solution the area of any peak corresponding to hydrocortisone is not greater than the area of the peak in the chromatogram obtained with working standard solution and the area of any other secondary peak is not greater than the area of the peak in the chromatogram obtained with working standard solution.	Complies
7.	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.	5301/vial 29/vial Complies

Analysis by 

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Approved by 



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
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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.		
10.	Assay: 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	99.23 mg	99.23%	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/AHS.

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