

**Pace***Add Pace To Health***Pace Biotech**

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

**Title****:****Certificate of Analysis Finished Product**

<b>Product Name</b>	<b>CORTICAN Injection</b>	<b>A.R. No.</b>	NB/FP/23/322
<b>Generic Name</b>	Hydrocortisone Sodium Succinate Injection IP 100mg	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	N23286D	<b>Sampled by</b>	Aakash
<b>Batch Size</b>	25,000 Vials	<b>Sampled on</b>	06/12/2023
<b>06/10/2023</b>	10/2023	<b>Date of Testing</b>	06/12/2023
<b>Exp. Date</b>	09/2025	<b>Date of Conditionally Release</b>	19/12/2023

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	<b>A.</b> 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>B.</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 $\pm 10\%$	-1.88% & +4.12%
4.	Average weight	Informative.	138.2 mg
5.	pH	6.5 to 8.0	7.43
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.	434/vial 5/vial  Complies



# Pace

Add Pace To Health

## Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	CORTICAN Injection	A.R. No.	NB/FP/23/322
Generic Name	Hydrocortisone Sodium Succinate Injection IP 100mg	Sampled qty.	45 Vials
Batch No.	N23286D	Sampled by	Aakash
Batch Size	25,000 Vials	Sampled on	06/12/2023
06/10/2023	10/2023	Date of Testing	06/12/2023
Exp. Date	09/2025	Date of Conditionally Release	19/12/2023

8.	Sterility	No microbial growth should be observed.		Under process	
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	98.65 mg	98.65%	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

Checked by

Approved by  
Quality Control Manager

