**Pace Biotech** 

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

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**Certificate of Analysis Finished Product** 

Title	: Certificate of Analysi	Certificate of Analysis Finished Product				
Product Name	Cortican Injection	A.R. No.	NB/FP/24/028			
	Hydrocortisone Sodium Succinate Injection IP	Sampled qty.	45 Vials			
Generic Name	100mg					
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
	Description	A white dry powder filled in clear	A white dry powder filled
		glass vial.	in clear glass vial.
2.	Identification by I.R	A. Determine by infrared absorption	Complies
	Assay	spectrophotometry compare the	
	Each alless vial Contains t	spectrum with that obtained with the	
		reference spectrum of	SCIPU 1 Laborato / Contractor
		hydrocortisone sodium succinate	dini cinutan
	isone Sodium, Suconate	IPRS or with the reference spectrum	05 0 to 105 0%
	IP	of hydrocortisone sodium succinate.	
	By TLC	B.The principal spot in the	Complies
		chromatogram obtained with the	and the second second
	a In the opinion of the unde	test solution corresponds to that in	
	a The Drug & Cosmidic Act	the chromatogram obtained with	Carried and searching and
	ALSO/AR	working standard solution.	2 200/ 8 +2 720/
3.	Uniformity of Weight	Average weight ±10%	-3.29% & +3.72%
4.	Average weight	Informative.	139.7 mg
5.	pH	6.5 to 8.0	7.66
5.	Related Substances	In the chromatogram obtained with	Complies
	Analysia by a	the test solution the area of any peak	- Stanson Ballinson
		corresponding to hydrocortisone is	- Commenter
		not greater than the area of the peak	No.
		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.	
7.	Particulate Matter		
	(a.) Sub-Visible particle		
	count		5301/vial
	(1.) Particles $\geq 10 \mu m$	NMT-6000/vial	29/vial
	(2.) Particles ≥25µm	NMT-600/vial	2.9/ 101
			Complies
	(b.) Visual	The solution is free from particles	
		of foreign matter particles that can	PAONTO
		be observed on visual inspection.	(A) (A)
			the maliny
	+ 1.:.h	Checked by	Approved by
	Analysis by	Checken by W	W I I I I I I I I I I I I I I I I I I I

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Approved b

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Exp. Date	02/2020			

8.	Sterility	No microbial	growth	should be	-	Complie	es
	the schollers	observed.		6	T	1 1 25	EII/ma of
9.	Bacterial Endotoxins	NMT-1.25	EU/m	ng of			EU/mg of
	the second s	Hydrocortisone.		Hydrocortisone.			
10.	Assay:	. and the shotest					
	Each glass vial Contains :						
Ingredients		Labeled	Found	1 % of 1	abeled	Limits %	of labeled
		Claim		amo	ount	amount	
Hydrocortisone Sodium Succinate (Sterile) IP		100 mg	99.23 m	.g 99.2	99.23% 95.0		105.0%
Eq. to Hydrocortisone		a faith and a second	Spal in			- Company	

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.

Analysis by

Checked by U