



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Cortican 100 mg	A.R. No.	FG/G/24A0119
Generic Name	Hydrocortisone Sodium Succinate Injection IP 100 mg	Sample Quantity	65 Vials
Batch No.:	AGD41007	Sample Received on	10/10/2024
Batch Size:	30200 Vials	Analysis Date	10/10/2024
Mfg. Date.	10/2024	Release Date	24/10/2024
Exp. Date	09/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	A White powder filled in a transparent 5 ml molded glass vial sealed with rubber stopper red coloured flip off having aluminium seal.	A White powder filled in a transparent 5 ml molded glass vial sealed with rubber stopper red coloured flip off having aluminium seal.		
2.	Identification:				
	a) By IR	The infrared absorption spectrum of sample should concordant with the spectrum of hydrocortisone sodium succinate reference or working standard or with the reference spectrum of hydrocortisone sodium succinate.	Complies		
	b) By TLC	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	Complies		
3.	Average filled weight	± 7.5% of Target filled weight.	134.62 mg		
4.	Uniformity of filled weight	± 10% of its average filled weight	Min: 132.04 mg ; Max: 137.75 mg -1.91% ; + 2.33%		
5.	pH	6.5 to 8.0	7.31		
6.	Particulate matter	The Sample Solution should be clear and free from any visible particles	The Sample Solution is clear and free from any visible particles.		
7.	Clarity of Solution	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Solid dissolve completely when, leaving no visible residue as undissolved matter.		
8.	Bacterial Endotoxins Tests	NMT 1.25 EU/mg of Hydrocortisone.	Less than 1.25 EU/mg		
9.	Sterility	Should be sterile	Sterile		
10.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Sterile Hydrocortisone Sodium succinate IP Eq. to Hydrocortisone	100 mg	Between 95.0 % to 105.0 % of stated amount of Hydrocortisone (Between 95.0 mg to 105.0 mg)	98.27 mg	98.27 %

Remarks: The above test parameters are complies/-not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Ramawadh Yadav
Designation	Executive	Head QC	Head - QA
Signature			
Date	24/10/2024	24/10/2024	24/10/2024