CERTIFICATE OF ANALYSIS

Product Name	**STERICORT 100** [HYDROCORTISONE SODIUM SUCCINATE FOR INJECTION USP 100MG]	Manufacture date	JUY-2022
Batch No.	7000822	Expiry date	JUY-2025
Strength	100 MG	Test date	28.07.2022
Batch Size	70,922 vials	Report date	12.08.2022
Reference	HYDSS –100 / 7000822	LC Number	
Manufacturer	M/s.Karnataka Antibiotics and Pharmaceuticals Limited		
Note : 10.00 kgs used for the batch Theoretical yield : 70.922 vials, the final batch quantity : 68,500 vials			

Sl. No	Item	Specification	Results
01.	Description	White or nearly white powder filled in 10 cc USP type III colourless glass vials, stoppered with 20 mm grey bromo butyl rubber closures and sealed with 20 mm tear off aluminium seals.	Nearly white powder filled in 10 cc USP type III colourless glass vials, stoppered with 20 mm grey bromo butyl rubber closures and sealed with 20 mm tear off aluminium seals.
02.	Identification		
	A. Infrared absorption spectrum	The infrared absorption spectrum of the test preparation exhibits maxima at the same wavelength as that of a similar preparation of USP Hydrocortisone hemisuccinate RS.	The infrared absorption spectrum of the test preparation exhibits maxima at the same wavelength as that of a similar preparation of USP Hydrocortisone hemisuccinate RS.
03.	Average weight	0.135 gm /vial. ± 10%	0.1465 gm/ vial (±10% = 0.1318 gm to 0.1611 gm)
04.	Uniformity of dosage unit	Acceptance value NMT 15	7.20
05.	pH	Bet. 7.0. & 8.0 %	7.42
06.	Loss on drying	NMT 2.0 % w/w	0.98 % w/w
07.	Bacterial Endotoxins	NMT 1.25 EU/MG	L.T. 1.25 EU/MG
08.	Sterility	To be sterile	Sterile
09.	Free Hydrocortisone	NMT 6.7% of the labelled amount of Hydrocortisone	0.962%
10.	Constituted Solution:		
	Completeness and clarity of solution	The solid should dissolve completely leaving no visible residue as undissolved matter when constituted.	The solid should dissolve completely leaving no visible residue as undissolved matter when constituted.
		The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injections contained in a similar container and examined in the same manner.	The constituted solution is clear.
11.	Particulate matter		
	By light obscuration Test	NMT 6000 Particles / container ≥10µm NMT 600 Particles / container ≥25µm	64.0 Particles / container 1.0 Particles / container
	By Visual Inspection:	The Solution shall be essentially free from particles of foreign matter that can be observed on visual inspection, when constituted as per the label.	The Solution is essentially free from particles of foreign matter that can be observed on visual inspection, when constituted as per the label.
12.	**Assay:** Hydrocortisone [As Hydrocortisone Sodium Succinate] Claim: 100 mg/vial	NLT 90.0% NMT 110.0%	104.917 mg/vial or 104.92 %

Conclusion: The batch meets the requirements of the USP.

Prepared by:	KU Anand	Authorized by	
Date:	12/08/2022	Date	12/08/2022