



UNITED BIOCEUTICALS PVT. LTD.

Plot No. 33C, Industrial Park-IV, Begumpur, Haridwar-249402,(Uttarakhand)

CERTIFICATE OF ANALYSIS

Product Name: IMMUNOSPORIN-50	Test SPC No.: UB/QC/STP3457
Generic Name: Cyclosporine Capsules IP 50 mg	
Marketed by: Healing Pharma	
Mfg. Lic No.: 94/UA/2017	Batch No.: C240151
Batch Size: 50,000 Caps	Pack Size : 10 x 1 x 10's
Sample Quantity: 60 Caps	Mfg. Date : 08/2024
Shelf Life : 24 Months	Expiry Date: 07/2026
	Report Date : 13.09.2024

Test	Specification	Results
Description	White to off white coloured powder filled in hard gelatin capsules having Blue/white cap & body.	Off white coloured powder filled in hard gelatin capsules having Blue/white cap & body.
Identification	By HPLC	Complies
Average Weight	285.0 mg $\pm$ 5.0% (270.8 to 299.3 mg)	276.4 mg
Average fill Weight	220.0 mg $\pm$ 5.0% (209.0 to 231.0 mg)	213.7 mg
Uniformity of Weight	Not more than two capsules deviates from $\pm$ 10 % and none deviates from $\pm$ 20% of average weight	Complies
Disintegration Test	NMT 30 Minutes	7:21 Minutes
Dissolution Test	NLT 85.0%	94.66% to 98.95%
Water Content	NMT 3.50%	1.41%
Assay: Each hard gelatin capsule contains: Cyclosporine IP 50 mg	45.00 mg to 55.00 mg 90.00% to 110.00%	49.45 mg 98.89%

OPINION: The sample **Complies/Does not Complies** as per Standard specification.

Analysed by:
Date:

Checked by:
Date:

Approved by:
Date: