Supermax

Supermax Drugs & Pharmaceuticals Pvt. Ltd.

II-1231, DSIDC Industrial Complex, Narela, Delhi 110040

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

(The Drugs & Cosmetics Act 1940 & Rules Made Thereunder)

Name of Sample	IMSTATIN 500 INJECTION 1G	Certificate No.	BF-26072202
Generic Name	Imipenem & Cilastatin Injection IP 1G	Receipt Date	22-07-2026
Mfd. By	Supermax Drugs & Pharmaceuticals Pvt. Ltd., Delhi-110040	Sample Qty	30 vials
Batch No.	IMTN-01	Batch Size	10100 vials
Mfg. Date	06/2026	Exp. Date	05 2028
Reference	Indian Pharmacopoeia (IP)		

ANALYSIS DATA

Test	Results	Specification / Limits
CHEMICAL ANALYSIS		
Description	Almost White powder filled in colourless glass vials	A White or almost white powder filled in colourless glass vials
Average weight	1112.68 mg	1008.0 mg to 1288.0mg
Uniformity of weight	Within limit	Not more than two of the individual weight deviate from the average weight by more than 10% and non deviates by more than 20%.
*Identification	Complies	In the assay the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
Particulate matter		
A. By Visual Inspection	The constituted solution is free from foreign particles that can be observed on visual inspection	The constituted solution should be free from foreign particles that can be observed on visual inspection
*B. By Light Obscuration	813.3 particles Container	≥ 10 µm NMT 6000 particles Container
Particle Count Test	6.7 particles/Container	≥ 25 µm NMT 600 particles Container
Clarity of solution A.	After constitution of injection solid dissolves completely, leaving no visible residue as undissolved matter.	After constitution of injection solid should dissolves completely, leaving no visible residue as undissolved matter.
B.	The constituted injection is not significantly less clear than an equal volume of the dilute or water for injections contained in a similar container and examined in the same manner.	The constituted injection should not significantly less clear than an equal volume of the dilute or water for injections contained in a similar container and examined in the same manner
pH	7.61	6.5 to 8.5
*Loss on drying	1.23% w/w	Not more than 3.5% w/w

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CERTIFICATE OF ANALYSIS
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Name of Sample	IMSTATIN 500 INJECTION 1G	Certificate No.	BF-26072702
Generic Name	Imipenem & Cilastatin Injection IP 1G	Receipt Date	22-07-2026
Mfd. By	Supermax Drugs & Pharmaceuticals Pvt. Ltd., Delhi-110040	Sample Qty	30 vials
Batch No.	IMTN-01	Batch Size	10100 vials
Mfg. Date	06/2026	Exp. Date	05 2028
Reference	Indian Pharmacopoeia (IP)		

***ASSAY / CONTENT:** Each vials on an average fill contains:

Ingredient	Result	Claim	Limit	Method
Imipenem eq. to Anhydrous Imipenem	508.81 mg	500.0 mg	450.0 mg to 575.0 mg	IP
Cilastatin Sodium eq. to Cilastatin	507.70 mg	500.0 mg	450.0 mg to 575.0 mg	IP

***BIOLOGICAL ANALYSIS**

Sterility	Complies with the test for sterility. (Vide Report no- BSF-26060301 Date- 18-06-2026)	To Sterile
Bacterial endotoxins	Less than 0.17 EU/mg of Imipenem & Cilastatin	Not more than 0.17EU mg of Imipenem & Cilastatin

Remark: In the estimated the sample referred above is of standard quality as defined in the Act & Rules made there under as per IP.

*Indicate the results referred from the Vide report no. BSF-26060301 (B.No. M-IMNM-12).

	ANALYZED BY	CHECKED BY	APPROVED BY
Name	Kundan Singh Bisht	Hari om	Sumer Singh
Signature			
Date	24-07-2026	24-07-2026	24-07-2026
Designation	QC Chemist	QC Manager	QA Manager

SUPERMAX DRUGS & PHARMACEUTICAL (P) LTD. QUALITY CONTROL DEPARTMENT