Pace Biotech

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

Add Pace To Health

:

Title

Certificate of Analysis Finished Product

Product Name	IMSTATIN 500 Injection	A.R. No.	BD/FP/23/580
Generic Name	Imipenem & Cilastatin Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	B23469N	Sampled by	Aakash
Batch Size	1000 Vials	Sampled on	05/12/2023
Mfg. Date	10/2023	Date of Testing	05/12/2023
Exp. Date	09/2025	Date of Release	20/12/2023

Description Identification Uniformity of Weight Average weight pH Loss on drying Particulate Matter	A white dry pow vial. In the Assay, th chromatogram of solution correspondent Chromatogram working standard Average weight Informative. 6.5 to 8.5 NMT- 3.5% w/w	e principal pea obtained with onds to the pea obtained w d solution.	ks in the the test	in clea	te dry powder filled r glass vial. Complies	
Uniformity of Weight Average weight pH Loss on drying	 chromatogram of solution correspondence of correspondence	obtained with onds to the pea obtained w d solution.	the test ak in the	-2		
Average weight pH Loss on drying	Informative. 6.5 to 8.5	±10%		-2	.66% & +1.17%	
pH Loss on drying	6.5 to 8.5				-2.66% & +1.17%	
Loss on drying			Informative.		1101.5 mg	
	NMT- 3.5% w/w	6.5 to 8.5		7.30		
Particulate Matter	NMT- 3.5% w/w		2.59%w/w			
			1			
(a.) Sub-Visible particle count (1.) Particles ≥10μm	NMT-6000/vial				570/vial	
(2.) Particles $\geq 25 \mu m$	NMT-600/ vial			20/vial		
(b.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.			Complies		
Sterility	No microbial growth should be observed.		Complies			
Bacterial Endotoxins	NMT- 0.17 EU/mg of Imipenem & Cilastatin.		Less than- 0.17 EU/mg of Imipenem & Cilastatin.			
Assay: Each glass vial Contains						
nts	Labeled Claim	Found				
1	Station of the		101			
nhydrous Imipenem	500 mg	506.24 mg	101.2	25%	90.0 to 115%	
ilastatin Sodium I.P lastatin Bicarbonate IP added as	500 mg	538.67 mg	107.7	107.73% 90.0 to 115%		
A E I I I	Assay: Each glass vial Contains ts ipenem I.P hydrous Imipenem lastatin Sodium I.P	Bacterial Endotoxins NMT- 0.17 EU/r Cilastatin. Assay: Each glass vial Contains ts Labeled Claim ipenem I.P hydrous Imipenem 500 mg lastatin Sodium I.P astatin 500 mg	Bacterial Endotoxins NMT- 0.17 EU/mg of Imipene Cilastatin. Assay: Each glass vial Contains ts Labeled Claim hydrous Imipenem 500 mg lastatin Sodium I.P astatin 500 mg 500 mg 538.67 mg	Bacterial Endotoxins NMT- 0.17 EU/mg of Imipenem & Cilastatin. Assay: Cach glass vial Contains ts Labeled Claim Found % of la amo ipenem I.P hydrous Imipenem 500 mg 506.24 mg 101.2 lastatin Sodium I.P astatin 500 mg 538.67 mg 107.7	Bacterial Endotoxins NMT- 0.17 EU/mg of Imipenem & Less the Imipener & Cilastatin. Assay: Cilastatin. Imipener & Imipener & Cilastatin. Assay: Labeled Claim Found % of labeled amount ts Labeled Claim Found 101.25% hydrous Imipenem 500 mg 538.67 mg 107.73%	

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 IPBP/USP/IHS.

Analysis by

Checked by