NOOTAN PHARMACEUTICALS

Village-Tipra, Barotiwala, Tehsil-Baddi, Solan (Dist.) H.P.

	CERTIFICATE OF ANALYSIS		
	Quality Control Department		
Name of the Product	PIMTAN INJECTION		
Generic Name	CEFEPIME FOR INJECTION USP 1g		
Batch No.	14003	A.R .No.	NFP/24-25/016
Mfg. Date	09/2024	Date of Testing	07/11/2024
Exp. Date	07/2027	Date of Release	21/11/2024
Batch Size	24800 vials	Qty. of Sample	22 Vials

S. No.	TESTS	SPECIFICATIONS	RESULTS
1	**Description**	White to pale yellow crystalline powder filled in clear glass vial , sealed with grey colored butyl rubber	White crystalline powder filled in clear glass vial , sealed with grey colored butyl rubber
2	**Identification** **B: By HPLC**	The retention time of the major peak in the chromatogram of the Assay preparation should be correspond to that in the chromatogram of the Standard preparation, as obtained in the Assay.	The retention time of the major peak in the chromatogram of the Assay preparation correspond to that in the chromatogram of the Standard preparation, as obtained in the Assay.
3.	**Reconstitution solution**	When Reconstituted with SWFI, solution should be clear & off white colour.	Solution is clear & off white.
3	**Average filled Weight**	1882 mg±3%	1883.1 mg
4	**Uniformity of Weight**	± % 5 Average weight	Complies
5	**pH**	Between 4.0 to 6.0	4.68
6	**Water**	Not More Than 4.0 %	2.65%
7	**Constitution Solution** A: Completeness B: Clarity of solution	A: The solid dissolves completely, leaving no visible residue as un dissolved matter. B: The constituted solution is not significantly less clear than an equal volume of the diluents or purified water contained in similar vessel and examined similarly.	A: The solid dissolves completely, no visible residue present. B: The constituted solution is clear

	Analyzed By	Checked By	Approved By
Name	Shivali Devi	Ram Swrup	Awadhesh Kumar
Signature	Shivali		Akumar
Date	21/11/2024	21/11/2024	21-11-2024

NOOTAN PHARMACEUTICALS

Village-Tipra, Barotiwala, Tehsil-Baddi, Solan (Dist.) H.P.

	CERTIFICATE OF ANALYSIS		
	Quality Control Department		
Name of the Product	PIMTAN INJECTION		
Generic Name	CEFEPIME FOR INJECTION USP 1g		
Batch No.	I4003	A.R .No.	NFP/24-25/016
Mfg. Date	09/2024	Date of Testing	07/11/2024
Exp. Date	07/2027	Date of Release	21/11/2024
Batch Size	24800 vials	Qty. of Sample	22 Vials

8	**Particulate matter** **A: Visible particles** **B: Particulate matter** **a: Particle ≥ 10 µm** **b: Particle ≥ 25 µm**	A: After reconstitution-Solution should be free from particles when examined visually. NMT 6000 NMT 600	The solution is essentially free from foreign matter that can be observed on visual inspection. Complies Complies
9	**Related compounds**	Related compound A – NMT 0.5% Related compound B- NMT 0.5% Other impurity – NMT 0.5%	Not Detected Not Detected Not Detected
10	**Assay:** **Each Vial Contains:** **Cefepime hydrochloride USP** **Eq. to Cefepime 1000mg**	900.0 mg to 1150.0 mg 90.0% to 115.0%	965.76 mg 96.58 % w/w
11	**Sterility**	Requirements when tested as directed for Membrane Filtration under Test for Sterility of the Product to be Examined.	Complies
12	**Bacterial Endotoxins**	Not more than 0.06 USP Endotoxin Unit per mg of Cefepime.	Less than 0.06EU/mg

Remark: The sample referred **Complies /~~does not Complies~~** with respect to above test as per **~~IP/~~USP/BP/~~IHS~~** Specification.

	Analyzed By	Checked By	Approved By
Name	Shivali Devi	Ram Swaroop	Awadhesh Kumar
Signature	Shivali		Akumar
Date	21/11/2024	21/11/2024	21-11-2024