

MAXMED LIFE SCIENCES PVT.LTD.

Plot No.54, Sector-IIDC, Sidcul,
Rudrapur (UTTARAKHAND)

QUALITY CONTROL DEPARTMENT (REPORT OF ANALYSIS)

Ref. No. & Date	FI-19BEI026/15.06.19		Test Report No.	BIFP190119	
Name of the Sample	Benzathine Benzylpenicillin injection 2400000 unit		Date of Receipt of Sample	15-06-2019	
Manufactured by	MAXMED		Manufactured for	FLAGSHIP BIOTECH	
Ref. To protocols of test	MLQC/STP/BI/FP007/IHS		Document No.	00	
Batch No.	D/M	D/E	Ref. Sampling plan	Sop no.MLQA-031	
19BEI026	06/2019	05/2021	Batch Size	Sample Qty.	Mfg.Lic.No.
			10200 Vial	50 Vial	150/UA/SC/P-2007

Name of Tests	Specifications	Result of Analysis
Description	A white or almost white powder filled in 20ml tubular clear glass vials USP type I with aluminium flipoff seal.	White powder filled in transparent glass vial.
Identification	A. By infrared spectrophotometer B. It responds to the tests for sodium	Complies
Average Fill Weight	1820mg \pm 2.0%	1819.54mg
Uniformity of dosage units	NMT 15.0%	2.69%
Water	Between 5.0% to 8.0%	6.74%
Constituted Solution	A: The solid dissolves completely, leaving no visible residue as undissolved matter. B: The Constituted solution is not significantly less clear than equal volume of the diluents or of water for injection contained in a similar container and examined similar manner.	Complies
Particulate Matter	The solution is essentially free from particles of foreign matter that can be observed on visual inspection	Complies
Sterility	Complies with the test for sterility	Complies
Bacterial endotoxins	NMT 0.13 EU/ml of Benzathine Benzyl penicillin	Less than 0.13 EU/ml of Benzathine Benzyl penicillin
Assay (By HPLC) Each vial contains: Benzathine Benzyl penicillin B.P. Eq. to Benzyl penicillin 2400000 Unit	2160,000 Units to 2640,000 Units	2452,214 Units

Opinion: In the opinion of the Undersigned the sample referred to above is **OF STANDARD QUALITY** in above respects. As per IHS.

Date: 29-06-2019

Chemist

Person In charge