



MAXMED LIFE SCIENCES PVT.LTD.
Plot No.54, Sector-IIDC, SIDCUL, Rudrapur (Uttarakhand)
Quality Control Department
CERTIFICATE OF ANALYSIS (Finished Product)

Brand Name	Benzathine Benzylpenicillin injection 1200000 unit		Page No. 1 of 1
Generic Name	Benzathine Benzylpenicillin injection 1200000 unit		
Mfg. Lic. No.	150/UA/SC/P-2007	A.R. No.	BIFP200119
Pack Size	1 x 10 ml Vial	Dosage Form	Injection
Manufactured by	Maxmed Lifesciences Pvt. Ltd	Specification No.	MLQC/STP/BI/FP017/IHS
Manufactured for	Maxmed Lifesciences Pvt. Ltd	Sample Received date	11/11/2020
Batch No.	20BEI041	Sample Quantity	50 Vials
Mfg. Date	11/2020	Batch Size	10200 Vials
Exp. date	10/2022	Release date	25/11/2020

Sr. No.	Name of Tests	Results	Specifications
1.	Description	A white or almost powder filled in 10 ml moulded clear glass vials with aluminium flip off seal.	A white or almost powder filled in 10 ml moulded clear glass vials with aluminium flip off seal.
2.	Identification(By HPLC)	In the Assay, the retention time of the principal peak in the chromatogram obtained with test solution should be correspond to those in the chromatogram obtained with Standard solution.	In the Assay, the retention time of the principal peak in the chromatogram obtained with test solution should be correspond to those in the chromatogram obtained with Standard solution.
3.	Average Fill Weight	915.8 mg	910mg \pm 5.0%
4.	Uniformity of dosage units	1.23	Acceptance value L1 is \leq 15.0
5.	Water	6.92%	Between 5.0% to 8.0%
6.	Constituted solution	A. The solid dissolves completely, leaving no visible residue as un dissolved 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.	Constitute the injection as directed on the label: A. The solid dissolve completely, leaving no visible residue as un dissolved matter. B. The constituted injection should not be significantly less clear than an equal volume of the diluents or of water for injection contained in a similar container and examined in the same manner.
	Particulate Matter (i) Visible particle	The solution is essentially free from particle of foreign matter that can be seen on visual inspection	Constitute the solution as directed on the label; The solution should be essentially free from particle of foreign matter that can be seen on visual inspection.

	Prepared by	Checked by	Approved by
Name	Vishal Sharma	H.S. Koush	Avinash Verma
Designation	Executive-CC	Head CC	Head CC
Signature			
Date	25/11/20	25/11/20	25/11/20



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Brand Name	Benzathine Benzylpenicillin injection 1200000 unit		Page No. 2 of 2
Generic Name	Benzathine Benzylpenicillin injection 1200000 unit		
Mfg. Lic. No.	150/UA/SC/P-2007	A.R. No.	BIFP200119
Pack Size	1 x 10 ml Vial	Dosage Form	Injection
Manufactured by	Maxmed Lifesciences Pvt. Ltd	Specification No.	MLQC/STP/BI/FP017/IHS
Manufactured for	Maxmed Lifesciences Pvt. Ltd	Sample Received date	11/11/2020
Batch No.	20BEI041	Sample Quantity	50 Vials
Mfg. Date	11/2020	Batch Size	10200 Vials
Exp. date	10/2022	Release date	25/11/2020

	Particulate Matter: (ii) Sub Visible Particles (By Light Obscuration particle count test) $\geq 10 \mu\text{m}$ $\geq 25 \mu\text{m}$	998.25 particles/container 31.87 particles/container	Not more than 6000 particles /container Not more than 600 particles/container
7.	Sterility	Sterile	Complies with the test for sterility
8.	Bacterial endotoxins	Less than 0.13 IU/ml of Benzathine Benzyl penicillin	NMT 0.13 EU/ml of Benzathine Benzyl penicillin
9.	Assay (By HPLC) Each vial contains: Benzathine Benzylpenicillin B.P 1200000 Unit	1210522 Unit	10,80,000 Units to 13,20,000 Units (90.0% to 110.0% of the labeled claim)

Storage Condition: Store in a dry, well ventilated place at a temperature not exceeding 25°C.

Shelf Life: 24 months when properly stored.

Conclusion: As per the received sample, batch is ~~qualified/ not qualified~~ for dispatch, according to USP-BP/IP/IH Specification.

	Prepared by	Checked by	Approved by
Name	Vishal Sharma	MSR	Avinash Verma
Designation	Executive - QC	Head QC	Head QA
Signature			
Date	25/11/20	25/11/20	25/11/20



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Brand Name	Benzathine Benzylpenicillin injection 1200000 unit		Page No. 1 of 1
Generic Name	Benzathine Benzylpenicillin injection 1200000 unit		
Mfg. Lic. No.	150/UA/SC/P-2007	A.R. No.	BIFP200120
Pack Size	1 x 10 ml Vial	Dosage Form	Injection
Manufactured by	Maxmed Lifesciences Pvt. Ltd	Specification No.	MLQC/STP/BI/FP017/IHS
Manufactured for	Maxmed Lifesciences Pvt. Ltd	Sample Received date	11/11/2020
Batch No.	20BEI042	Sample Quantity	50 Vials
Mfg. Date	11/2020	Batch Size	10200 Vials
Exp. date	10/2022	Release date	25/11/2020

Sr. No.	Name of Tests	Results	Specifications
1.	Description	A white or almost powder filled in 10 ml moulded clear glass vials with aluminium flip off seal.	A white or almost powder filled in 10 ml moulded clear glass vials with aluminium flip off seal.
2.	Identification(By HPLC)	In the Assay, the retention time of the principal peak in the chromatogram obtained with test solution should be correspond to those in the chromatogram obtained with Standard solution.	In the Assay, the retention time of the principal peak in the chromatogram obtained with test solution should be correspond to those in the chromatogram obtained with Standard solution.
3.	Average Fill Weight	912.6 mg	910mg \pm 5.0%
4.	Uniformity of dosage units	2.24	Acceptance value L1 is \leq 15.0
5.	Water	6.82%	Between 5.0% to 8.0%
6.	Constituted solution	A. The solid dissolves completely, leaving no visible residue as un dissolved 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.	Constitute the injection as directed on the label: A. The solid dissolve completely, leaving no visible residue as un dissolved matter. B. The constituted injection should not be significantly less clear than an equal volume of the diluents or of water for injection contained in a similar container and examined in the same manner.
	Particulate Matter (i) Visible particle	The solution is essentially free from particle of foreign matter that can be seen on visual inspection	Constitute the solution as directed on the label; The solution should be essentially free from particle of foreign matter that can be seen on visual inspection.

	Prepared by	Checked by	Approved by
Name	Vishal sharma	Nis Karp	Avinash verma
Designation	Executive-oc	Head qc	Head QA
Signature			
Date	25/11/20	25/11/20	25/11/20



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Brand Name	Benzathine Benzylpenicillin injection 1200000 unit		Page No. 2 of 2
Generic Name	Benzathine Benzylpenicillin injection 1200000 unit		
Mfg. Lic. No.	150/UA/SC/P-2007	A.R. No.	BIFP200120
Pack Size	1 x 10 ml Vial	Dosage Form	Injection
Manufactured by	Maxmed Lifesciences Pvt. Ltd	Specification No.	MLQC/STP/BI/FP017/IHS
Manufactured for	Maxmed Lifesciences Pvt. Ltd	Sample Received date	11/11/2020
Batch No.	20BEI042	Sample Quantity	50 Vials
Mfg. Date	11/2020	Batch Size	10200 Vials
Exp. date	10/2022	Release date	25/11/2020

	Particulate Matter: (ii) Sub Visible Particles (By Light Obscuration particle count test) $\geq 10 \mu\text{m}$ $\geq 25 \mu\text{m}$	1002.5 particles/container 19.56 particles/container	Not more than 6000 particles /container Not more than 600 particles/container
7.	Sterility	Sterile	Complies with the test for sterility
8.	Bacterial endotoxins	Less than 0.13 IU/ml of Benzathine Benzyl penicillin	NMT 0.13 EU/ml of Benzathine Benzyl penicillin
	Assay (By HPLC) Each vial contains: Benzathine Benzylpenicillin B.P 1200000 Unit	1220687 Unit	10,80,000 Units to 13,20,000 Units (90.0% to 110.0% of the labeled claim)

Storage Condition: Store in a dry, well ventilated place at a temperature not exceeding 25°C.

Shelf Life: 24 months when properly stored.

Conclusion: As per the received sample, batch is qualified/ not qualified for dispatch, according to USP /BP/IP/IH Specification.

	Prepared by	Checked by	Approved by
Name	Vishal Sharma	Nishant	Avinash yerna
Designation	Executive-QC	Head QC	Head QA
Signature			
Date	25/11/20	25/11/20	25/11/20



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Brand Name	Benzathine Benzylpenicillin injection 1200000 unit		Page No. 1 of 1
Generic Name	Benzathine Benzylpenicillin injection 1200000 unit		
Mfg. Lic. No.	150/UA/SC/P-2007	A.R. No.	BIFP200121
Pack Size	1 x 10 ml Vial	Dosage Form	Injection
Manufactured by	Maxmed Lifesciences Pvt. Ltd	Specification No.	MLQC/STP/BI/FP017/IHS
Manufactured for	Maxmed Lifesciences Pvt. Ltd	Sample Received date	11/11/2020
Batch No.	20BEI043	Sample Quantity	50 Vials
Mfg. Date	11/2020	Batch Size	10200 Vials
Exp. date	10/2022	Release date	25/11/2020

Sr. No.	Name of Tests	Results	Specifications
1.	Description	A white or almost powder filled in 10 ml moulded clear glass vials with aluminium flip off seal.	A white or almost powder filled in 10 ml moulded clear glass vials with aluminium flip off seal.
2.	Identification(By HPLC)	In the Assay, the retention time of the principal peak in the chromatogram obtained with test solution should be correspond to those in the chromatogram obtained with Standard solution.	In the Assay, the retention time of the principal peak in the chromatogram obtained with test solution should be correspond to those in the chromatogram obtained with Standard solution.
3.	Average Fill Weight	921.41 mg	910mg \pm 5.0%
4.	Uniformity of dosage units	1.74	Acceptance value L1 is \leq 15.0
5.	Water	6.99%	Between 5.0% to 8.0%
6.	Constituted solution	A. The solid dissolves completely, leaving no visible residue as un dissolved 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.	Constitute the injection as directed on the label: A. The solid dissolve completely, leaving no visible residue as un dissolved matter. B. The constituted injection should not be significantly less clear than an equal volume of the diluents or of water for injection contained in a similar container and examined in the same manner.
	Particulate Matter (i) Visible particle	The solution is essentially free from particle of foreign matter that can be seen on visual inspection	Constitute the solution as directed on the label; The solution should be essentially free from particle of foreign matter that can be seen on visual inspection.

	Prepared by	Checked by	Approved by
Name	Vishal Sharma	Nisha	Avirash Verma
Designation	Executive QC	Head QC	Head QA
Signature			
Date	25/11/20	25/11/20	25/11/20



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Brand Name	Benzathine Benzylpenicillin injection 1200000 unit		Page No. 2 of 2
Generic Name	Benzathine Benzylpenicillin injection 1200000 unit		
Mfg. Lic. No.	150/UA/SC/P-2007	A.R. No.	BIFP200121
Pack Size	1 x 10 ml Vial	Dosage Form	Injection
Manufactured by	Maxmed Lifesciences Pvt. Ltd	Specification No.	MLQC/STP/BI/FP017/IHS
Manufactured for	Maxmed Lifesciences Pvt. Ltd	Sample Received date	11/11/2020
Batch No.	20BEI043	Sample Quantity	50 Vials
Mfg. Date	11/2020	Batch Size	10200 Vials
Exp. date	10/2022	Release date	25/11/2020

	Particulate Matter: (ii) Sub Visible Particles (By Light Obscuration particle count test) ≥ 10 µm ≥ 25µm	1124.21 particles/container 35.40 particles/container	Not more than 6000 particles /container Not more than 600 particles/container
7.	Sterility	Sterile	Complies with the test for sterility
8.	Bacterial endotoxins	Less than 0.13 IU/ml of Benzathine Benzyl penicillin	NMT 0.13 EU/ml of Benzathine Benzyl penicillin
9.	Assay (By HPLC) Each vial contains: Benzathine Benzylpenicillin B.P 1200000 Unit	1211758 Unit	10,80,000 Units to 13,20,000 Units (90.0% to 110.0% of the labeled claim)

Storage Condition: Store in a dry, well ventilated place at a temperature not exceeding 25°C.

Shelf Life: 24 months when properly stored.

Conclusion: As per the received sample, batch is **qualified/ not qualified** for dispatch, according to USP/ BP/ IP/ IHS Specification.

	Prepared by	Checked by	Approved by
Name	Vishal Sharma	Milind	Anusha verma
Designation	Executive- QC	Head QC	Head QA
Signature			
Date	25/11/20	25/11/20	25/11/20