

CERTIFICATE OF ANALYSIS

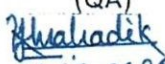
Product Name	Metronidazole Benzoate USP		
Batch No.	MEBR26002	A.R. No.	BRD/26/07/006
Mfg. Date	Jun-2026	Re-test Date	May-2029
Molecular Formula	C ₁₃ H ₁₃ N ₃ O ₄	Molecular Weight	275.26gm/mol
Batch Size	150.040kg	CAS.No.	13182-89-3
Storage Condition	Preserve in well-closed, light-resistant containers. Store at 25°C. excursions permitted between 15° and 30°.		

TESTS	SPECIFICATION	RESULTS
Appearance	White to slightly yellow, crystalline powder.	White crystalline powder.
Solubility	Freely soluble in Methylene chloride; soluble in acetone, slightly soluble in alcohol, very slightly soluble in ethyl ether, practically insoluble in water.	Complies
Identification		
a) By IR	The IR spectrum of sample should be match with Metronidazole Benzoate reference material or working standard.	Complies
b) By TLC	The principal spot of the sample solution corresponds to that of standard solution A, as obtained in the test for organic impurities.	Complies
Residue on ignition	NMT 0.1 %	0.04%
Organic impurities by TLC	No secondary spot of the Sample solution is larger or more intense than the principal spot of Standard solution A (0.5%); and NMT three spots, excluding the principal spot, of the Sample solution are larger or more intense than the principal spot of Standard solution B (0.2%).	Complies
Acidity	NMT 0.25 mL is required to produce a color change.	0.22ml
Loss on drying	NMT 0.5 %	0.15 %
Assay by Titrimetric	NLT 98.5% and NMT101.0% of Metronidazole Benzoate C ₁₃ H ₁₃ N ₃ O ₄ , calculated on the dried basis.	100.9 %

Additional Test:
Residual Solvents (by GC)

Acetonitrile	NMT 410 ppm	Not Detected
Dichloromethane	NMT 600 ppm	Not Detected
N, N-Dimethylformamide	NMT 880 ppm	Not Detected
Pyridine	Should be absent	Not Detected
Formaldehyde	Should be absent	Not Detected
pH	5.0 to 7.0 (1 g in 100 mL)	6.71
Melting range	98°C to 102°C	99.1°C to 99.6°C

 Remarks: The product complies / ~~does not comply~~ above tests as per USP specifications.

Responsibility	Prepared By (QC)	Checked By (QC)	Approved By (QC)	Approved By (QA)
Sign / Date	 09-07-2026	 09-07-2026	 09-07-2026	 09-07-2026

