

CONCORD BIOTECH LIMITED

Regd. Office & Plant : 1482-1486, Trasad Road, Dholka, Dist. Ahmedabad-382225. (India)
Phones : +91-2714-222604, 398200 Fax : +91-2714-222504 Website : www.concordbiotech.com

CERTIFICATE OF ANALYSIS

Product	MITOMYCIN Ph.Eur.	A.R.No.	CBL-49421005A
Batch No.	49421005	Mfg. Date	Mar 2021
Batch size	200.0g	Retest Date	Feb 2024

S.N.	Tests	Specifications	Observations
1	Appearance	Blue-violet crystals or crystalline powder.	Blue-violet crystalline powder.
2	Solubility	Slightly soluble in water and in Acetone, freely soluble in Dimethylacetamide, sparingly soluble in Methanol.	Slightly soluble in water and in Acetone, freely soluble in Dimethylacetamide, sparingly soluble in Methanol.
3	Identifications (a) By IR	The infrared absorption spectrum of test preparation should be concordant with the reference / working standard preparation of Mitomycin.	The infrared absorption spectrum of test preparation is concordant with the working standard preparation of Mitomycin.
	(b) By HPLC	The retention time of the principal peak in the chromatogram obtained with the test solution corresponds to that of the principal peak in the chromatogram obtained with reference solution(a) as obtained in the Assay.	Std. RT : 8.6 min Test RT : 8.6 min Complies
4	Water (By KF)	Maximum 2.5 %	0.59 %
5	pH	5.5 - 7.5	6.4
6	Related substances (by HPLC)		
	Cinnamamide	NMT 0.5 %	Below disregard limit
	Mitomycin A	NMT 0.5 %	Below disregard limit
	Mitomycin B	NMT 0.5 %	Below disregard limit
	Albomitomycin C	NMT 0.5 %	0.13 %
	Any other impurity	NMT 0.15 %	0.11 %
	Total impurities	NMT 2.0 %	0.66 %
7	Assay (By HPLC) [Calculated on anhydrous substance]	97.0 % to 102.0 %	97.8 %
8	Bacterial Endotoxins	NMT 10.0 IU/mg	Less than 10.0 IU/mg
Additional test:			
9	Residual solvents (By GC-MS)		
	Methanol	NMT 3000 ppm	180 ppm
	Isopropyl alcohol	NMT 5000 ppm	1828 ppm
	Dichloromethane	NMT 600 ppm	Below detection limit
	Ethyl acetate	NMT 5000 ppm	116 ppm

Storage: Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°C.

Remarks: The material complies as per Ph.Eur. and in house specification no.: SPC/QC/FP/R/117-01.

Date of Report: Apr 13, 2021

Compiled By (QC)

Date: 13.04.2021
(A.J.kanzariya-Sr. Manager)

Checked By (QC)

Date: 13/04/2021
(S.K. Jha-Sr. GM)

Approved By (QA)

Date: 14/04/2021
(Tapas Saha-GM)

MITOMYCIN Ph.Eur. (Non - Sterile Bulk)	
CAS No. : [50-07-7]	Batch No. : 49421005
Mfg. Lic. No. : G/28/1282	Mfg. Date : Mar 2021
	Retest Date : Feb 2024
Container No. : 02 of 03	Gross Wt. : 166.8 gm
	Tare Wt. : 150.8 gm
	Net Wt. : 16.0 gm
Storage: Preserve in tight, light-resistant containers. Store at 25°C, excursions permitted between 15°C and 30°C.	
Manufactured by CONCORD BIOTECH LIMITED 1482-1486, TRASAD ROAD, DHOLKA, DISTRICT- AHMEDABAD PIN CODE - 382 225, INDIA	

Master Label No.: L-49-03-01