



MYLAN LABORATORIES LIMITED
Plot No. 11,12 and 13, Indore SEZ Pharma Zone,
Phase –II, sector –III, Pithampur - 454775,
Dist: Dhar, Madhya Pradesh, India.

CERTIFICATE OF ANALYSIS
(WORKING STANDARD)

Name:: Emtricitabine

Source Batch No.	EMBF220203	W.S. A.R. No.	MLPWSD23000004
Date of Standardisation	Feb 10 2023 1:28PM	Standardized against	Emtricitabine USPRS Batch No-R101B1
Storage Condition	Control Room Temperature	Validity	Jan 30, 2024
STP No.	RMPECB585-06	Ref. Specification	RMSECB585-08

S. No.	TEST	SPECIFICATION	RESULTS
1	Description	White to off-white powder.	Off white powder.
2	Identification (By Infrared spectroscopy)	The infrared spectrum of the sample in potassium bromide dispersion should exhibit maxima only at the same wavelengths as that of a similar preparation of Emtricitabine working standard.	The infrared spectrum of the sample in potassium bromide dispersion exhibit maxima at the same wavelengths as that of a similar preparation of Emtricitabine RS
3	Loss on Drying	Not more than 0.50% w/w	0.12 % w/w
4	Assay (By HPLC)	Not less than 98.0% w/w and not more than 102.0% w/w of $C_8H_{10}FN_{3/2}SO_3$, on dried basis.	On 'dried basis':100.5 % w/w On 'as-is basis':100.3 % w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	SANDEEP KUMAR.PARDHI	Approved By	Sharad kumar.Singh
Checked On	Feb 10 2023 10:00AM	Approved On	Feb 10 2023 1:28PM
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