

QUALITY CONTROL DEPARTMENT
[Certificate of Analysis Finished Product]
 (FORM 39, RULE 150 E (F) THE DRUG AND
 COSMETIC ACT, 1940 AND THE RULES THERE UNDER)

Product Name	: Entecavir-0.5 Tablets	AR Number	: FP-10-2024/0939
Generic Name	: Entecavir Tablets IP 0.5mg	Sample Quantity	: 100 Tablets
Batch No.	: KTB563B	Manufactured By	: Kureasia pharma Pvt. Ltd.
Batch Size	: 0.51 Lac	Manufactured For	: Healing Pharma India Pvt Ltd.
Date of Received	: 09/10/2024	Manufacturing Date	: 09/2024
Date of Analysis	: 09/10/2024	Expiry Date	: 08/2026
Mfg. Lic. No.	: 20/UA/2023 & 18/UA/SC/P-2023	Date of Completion	: 17/10/2024
Reference Protocol No	: KP/QC/FPS/219		

Sr. No	TEST PARAMETER	OBSERVATION	SPECIFICATIONS
1.	Description	White, round, biconvex, film coated tablets.	White, round, biconvex, film coated tablets.
2.	Identification (By High Performance Liquid Chromatography)	Meet the Requirement	In the Assay, the retention time of principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3.	Dissolution (By High Performance Liquid Chromatography)	94.96% to 104.89%	Q. Not less than 75 per cent of the stated amount of $C_{12}H_{15}N_5O_3$.
4.	Related Substance (By High Performance Liquid Chromatography)	0.27% 0.27%	The area of any secondary peak is not more than 0.5 per cent. The sum of areas of all the secondary peaks is not more than 1.0 per cent.
5.	Uniformity of Content (By High Performance Liquid Chromatography)	97.48% to 101.93%	85.00% to 115.00% of labeled amount of Entecavir.
6.	Assay : (By High Performance Liquid Chromatography) Each film coated tablets contains: Entecavir IP 0.5 mg (As monohydrate)	0.51mg	Shelf Life Limit: Not less than 0.45 mg and Not more than 0.55 mg. (Not less than 90.00% and not more than 110.00% of Label Claim) Release Limit: (Not less than 95.00% and not more than 105.00% of Label Claim) Not less than 0.475mg and not more than 0.525 mg.

ADDITIONAL TEST

7.	Average Weight	161.11 mg	160.00 mg $\pm$ 7.5 %
8.	Uniformity of Weight	-3.36% to + 2.97 %	Not more than 2 of the individual weight deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15.0% of the average weight.

Remark: Product complies / does not complies as per IP/BP/USP/HP specification.

Analyzed By :	Reviewed By :	Approved by
Sign/ Date	Sign/Date	Sign/Date