



STAFFORD LABORATORIES PVT. LTD.

KH.NO. 143, RAIPUR INDUSTRIAL AREA, RAIPUR, BHAGWANPUR, ROORKEE, DISTT.HARIDWAR (U.K.)
Mfg.Licence No. : 110/UA/SC/P-2006, 110/UA/2006

QUALITY CONTROL DEPARTMENT

(Certificate of analysis of finish product)
(The Drugs & Cosmetics Act 1940 and the Rules thereunder)

Sample : Entecavir 0.5 mg
Generic Name: Entecavir Tablets IP 0.5 mg
Mfg.&Supp.By: STAFFORD LABORATORIES PVT.LTD
Batch No. : ST-24161 Mfg.Dt.: May., 2024
Batch Size : 50000 TABS Exp.Dt.: Apr., 2026

Report No.: ST/161/24-25
Ref. No. : STF-24/161
Rcpt.Date : 25-05-2024
Sample Qty: 160 TABS

CERTIFICATE OF ANALYSIS

Description : A white coloured round shape biconvex film coated tablet
Score on a side.

Identification : Positive for Entecavir IP

Weight of 20 tablets : 4.0640 gm

Average weight : 203.2 mg

Uniformity of weight : Within Limit $\pm 7.5\%$

Dissolution : 82.70% (NLT-75%)

Assay:

Each film coated tablet contains:

	Claim	observed	Limit	Protocol
Entecavir Monohydrate IP				
Eq.to Entecavir	0.5 mg	0.497 mg	0.45-0.55.0mg	IP

Report : In the opinion of the undersigned, the sample referred to above is
of standard quality as defined in the act and the Rules made
there under.

Date: 27-05-2024

Analysed By: *An*

Testing Incharge:

