



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 : Enteclude 0.5
Generic Name: Entecavir Tablets IP 0.5 mg
Mfg.&Supp.By: STAFFORD LABORATORIES PVT.LTD
Batch No. : ST-231040 Mfg.Dt.: Nov.,2023
Batch Size : 45000 TABS Exp.Dt.: Oct.,2025

Report No.: ST/1040/23-24
Ref. No. : STF-23/1040
Rcpt.Date : 02-11-2023
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 : 4.1400 gm

Average weight : 207.0 mg

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

Dissolution : 81.50% (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: 04-11-2023

Analysed By:

Testing Incharge:

