

BIOALTUS PHARMACEUTICALS PVT.LTD.
19-20 Industrial Area, Baddi -173205 Distt. Solan
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

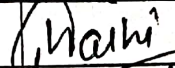
Product Name	Tacrolimus Capsules IP 1mg (TACROHEAL 1)	A.R. No.	BRDII/09/24/BD/0991CPF
Master/FG B. No.	BD241579/BD241579A	Master/FG B. Size	152857Caps/0.94 Lac
Mfd. By	Self	Sample Qty.	60 Capsules
MFD.	AUG.2024	Date of Receipt	24/09/2024
EXP.	JUL.2026	Date of Release	24/09/2024

RESULTS OF ANALYSIS

Reference to Protocol : IP

S.No.	Test	Results	Specification
01.	Description	Yellow cap & body hard gelatin capsule filled with white powder.	Yellow cap & body hard gelatin capsule filled with white powder.
02.	*Identification (By HPLC)	Complies	To comply
03.	Average weight	0.28160 gm	0.2780 gm $\pm$ 7.5 %
04.	Average fill weight	0.23132 gm	0.2300 gm $\pm$ 10.0 %
05.	Uniformity of fill weight	Min. 0.2259 gm Max. 0.2383 gm	$\pm$ 10.0 % of average fill weight
06.	*Uniformity of content	Min.101.12% Max. 105.91% average content 1.03mg	NLT 85% & NMT 115% of the average content
07.	*Dissolution (By HPLC)	Min.90.2 %, Max.101.6 % Mean.96.1%,	Q. NLT 80 %
08.	#Related Substance (By HPLC) I. Tacrolimus diene II. The area of any peak due to tacrolimus regioisomer III. Tacrolimus impurity A IV. The area of any secondary peak V. Sum of all the secondary peaks excluding tacrolimus open ring & tacrolimus 19 epimer Related Substance (B) (By HPLC) Tacrolimus 8-epimer Any other impurity Sum of all impurity	Not detected Not detected Not detected Not detected Not detected Not detected Not detected Not detected	NMT 0.3% NMT 0.5% NMT 0.3% NMT 0.2% NMT 1.0% NMT 0.5% NMT 0.2% NMT 1.5%
09.	*Assay (By HPLC) Each Hard gelatin capsules contains: Tacrolimus IP 1mg	1.0132 mg (101.3%)	NLT 0.93 mg & NMT 1.05mg (NLT 93.0 % & NMT 105.0 %)

Remark: In the opinion of the undersigned, the sample referred to above is of standard quality / is not of standard quality as defined in the Act and the Rules made there under for the reasons given below:
Complies as per IP No. BRDII/QC/FPS/398C2 *Test refer to oxigenLabReportNo.OALB240905032&OALB240912054
Test refer to Vorick Lab Report No.VAF240912219

Prepared By		Checked By		Approved By	
Date	24/09/2024	Date	24/09/2024	Date	24/09/2024