BIOALTUS PHARMACEUTICALS PVT.LTD.

19-20 Industrial Area, Baddi -173205 Distt. Solan

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	Tacrolimus Capsules IP 0.5 mg (TACROHEAL 0.5)	A.R. No.	BRDII/08/24/BD/0922CPF
Master/FG B.No.	BD241578/BD241578A	Master/FG B.Size	1.50 Lac/1.0 Lac
Mfd. By	Self	Sample Qty.	60 Capsules
MFD.	AUG.2024	Date of Receipt	11/09/2024
EXP.	JUL.2026	Date of Release	11/09/2024

RESULTS OF ANALYSIS

Reference to Protocol : IP

S.No.	Test	Results	Specification
01.	Description	Blue cap & White body hard gelatin capsule filled with white powder.	Blue cap & White body hard gelatin capsule filled with white powder.
02.	*Identification (By HPLC)	Complies	To comply
03.	Average weight	0.28066 gm	0.2780 gm ± 7.5 %
04.	Average fill weight	0.23061 gm	0.2300 gm ± 10.0 %
05.	Uniformity of fill weight	Min. 0.2257 gm Max. 0.2348 gm	±10.0 % of average fill weight
06	*Uniformity of content	Min.98.01 % Max. 106.39 % average content 0.510mg	NLT 85% & NMT 115% of the average content
07.	*Dissolution (By HPLC)	Min.89.1 %, Max. 97.5 % Mean 94.5 %,	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	 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%
09.	*Assay(By HPLC) Each Hard gelatin capsules contains: Tacrolimus IP 0.5 mg	0.4995 mg (99.9 %)	NLT 0.47 mg & NMT 0.53mg (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.OALB240830026&OALB240905128** **#Test refer to Vorick Lab Report No.VAF240906212**

Prepared By		Checked By		Approved By	
Date	11/09/2024	Date	11/09/2024	Date	11/09/2024