



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

CERTIFICATE OF ANALYSIS

Product Name	Sacubitril 24 mg & Valsartan 26 mg Tablets (Sacufox V 50)	A.R. No.	BRDII/06/25/BD/0576TF
Master/FG.B.No.	BD251244/BD251244B	Master/FG.B.Size	7.70 Lac/2.10 Lac
Mfd. By	Self	Sample Qty.	94 Tablets
MFG.	JUN.2025	Date of Receipt	26/06/2025
EXP.	MAY 2027	Date of Release	28/06/2025

RESULTS OF ANALYSIS

Reference to Protocol : In House Specification			
S.No.	Test	Result	Specification
1.	Description	Light Pink coloured elongated biconvex film coated tablet plain on both sides.	Light Pink coloured elongated biconvex film coated tablet plain on both sides.
2.	*Identification (By HPLC) For Sacubitril For Valsartan	Complies Complies	To Comply To Comply
3.	Average weight	0.20478 gm	0.2050 gm \pm 3%
4.	Disintegration	Min. 12 minute, 31 seconds Max. 13 minute, 31 seconds	NMT 30 minutes
5.	Uniformity of weight	Min.0.2033 gm, Max.0.2072 gm	\pm 7.5% of average weight
6.	Dissolution (By HPLC) For Sacubitril For Valsartan	Min. 84.90 %, Max. 97.93 % Mean 93.90 % Min. 90.06 %, Max. 104.17 % Mean 100.01 %	Q.NLT 75% Q.NLT 75%
7.	*Related Substances (By HPLC) Di- Acid Impurity Methyl Impurity Cyclic Impurity Maleic Impurity Any Individual unknown Impurity Total Impurities	Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected	NMT 1.0 % NMT 1.0 % NMT 1.0 % NMT 1.0 % NMT 0.5 % NMT 2.5 %
8.	Assay (By HPLC) Each Film coated tablet contains: Sacubitril Sodium 24 mg Eqv. to Sacubitril Valsartan IP 26 mg	23.76 mg (98.98 %) 27.27 mg (104.89 %)	NLT 21.6 mg & NMT 26.4mg (NLT 90.0% & NMT 110.0%) NLT 23.4 mg & NMT 28.6 mg (NLT 90.0% & NMT 110.0 %)

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 In House Specification No. (BRDII/QC/FPS/344F1)

*Tests refer to Vorick Lab Report No. VAF250626207

	Prepared By	Checked By	Approved By
Name	Shani Rana	Priyanka	Name :- Harpreet Kaur
Designation	QC Officer	Reviewer	Designation :- Manager Q.C.
Sign / Date	 28/06/2025	 28/06/2025	Sign./Date :- 28/06/2025

Qualification :- B.Pharmacy
Registration No :- 48657
State of Registration :- Punjab