

BIOALTUS PHARMACEUTICALS PVT. LTD.

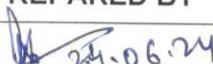
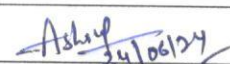
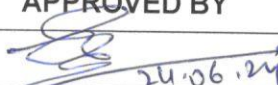
At : E-2, Sara Industrial Estate, Central Hope Town,
Rampur, Selaqui, Dehradun - 248197 (Uttarakhand)

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS FINISH PRODUCT

Product Name	Sacubrook-V 25 mg		
Generic Name	Sacubitril & Valsartan Tablets 25 mg		
Product Batch No.	BKT240004	Report No.	IPL/FP/241831
Mfg. Date	Jun.2024	Expiry Date	May 2026
Batch Size	1.0 Lac	Sample Qty.	50 Tablets
STP No.	In House	STS No.	In House
Date of Receipt	18/06/24	Date of Completion	24/06/24

S.No.	Tests	Specification	Result
1.	Description	Light yellow colour, round shape, biconvex, film coated tablets plain on one side and breakline on other side.	Light yellow colour, round shape, biconvex, film coated tablets plain on one side and breakline on other side.
2.	Identification For Sacubitril & valsartan (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with reference solution.	Passes the test
3.	Average Weight	124 mg $\pm$ 7.5%	124.50 mg
4.	Uniformity of weight	Limits $\pm$ 7.5 % of average weight	-3.46% to +3.32%
5.	Dissolution (By HPLC)		
	For Sacubitril	Not less than 75% (Q)	85.03% to 90.44%
	For Valsartan	Not less than 75% (Q)	88.92% to 92.94%
6.	Disintegration Test	Not more than 30 minutes	02 minutes
7.	Assay (HPLC) Each film coated tablet contains: Sacubitril 12 mg Valsartan 13 mg	10.8 mg to 13.2 mg (90% to 110% of the label claim) 11.7 mg to 14.3 mg (90% to 110% of the label claim)	11.351 mg (94.59%) 12.248 mg (94.21%)

Remark: The sample complies/does not complies as per Specification.

	PREPARED BY	REVIEWED BY	APPROVED BY
SIGNATURE/ DATE	 24.06.24	 24/06/24	 24.06.24
NAME	Nagma	Ashish Singh	R.K. Rajput
DESIGNATION	Officer QC	Sr. Executive QC	Manager-QC