



UNITED BIOCEUTICALS PVT. LTD.
Plot No. 33C, Industrial Park-IV, Begumpur, Haridwar-249402, (Uttarakhand)

CERTIFICATE OF ANALYSIS

Product Name: SACUFOX-V 100		Test SPC No.: UB/QC/STP3265
Generic Name: Sacubitril and Valsartan Tablets		
Marketed by: American remedies Healthcare Pvt. Ltd.		
Mfg. Lic No.: 94/UA/2017		Batch No.: T240047
Batch Size: 1,41,000 Tabs	Pack Size: 10 x 14's	A. R. No.: FPT24250183
Sample Quantity: 60 Tabs	Mfg. Date: 04/2024	Expiry Date: 03/2026
Shelf Life: 24 Months	Sampling Date: 25.04.2024	Report Date: 26.04.2024

Test	Specification	Results
Description	Light brown coloured, elongated, biconvex, film coated tablets.	Light brown coloured, elongated, biconvex, film coated tablets.
Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the assay
Average Weight	215.0 mg \pm 3.0% (208.6 to 221.5 mg)	217.4 mg
Uniformity of Weight	Not more than two tablets deviate from \pm 7.5% and none deviates from \pm 15% of average weight	Complies
Disintegration Test	NMT 30 Minutes	4:52 Minutes
Assay: Each film coated tablet contains: 49 mg Sacubitril and 51 mg Valsartan as Sodium salt complex	90.00 mg to 110.00 mg 90.00% to 110.00%	99.90 mg 99.90%

OPINION: The sample **Complies**/~~Does not Complies~~ as per Standard specification.

Analysed by:
Date:

26/04/2024

Checked by:
Date:

26/04/2024

Approved by:
Date:

26/04/2024