

UNITED BIOCEUTICALS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

Product Name: SACUFOX-V 50 Test SPC No.: UB/QC/STP3281

Generic Name: Sacubitril and Valsartan Tablets

Marketed by: American remedies Healthcare Pvt. Ltd.

Mfg. Lic No.: 94/UA/2017

Batch No.: T241254

Batch Size: 2,10,000 Tabs

Pack Size: 10 x 14's

A. R. No.: FPT24251418

Sample Quantity: 60 Tabs Mfg. Date: 08/2024 Expiry Date: 07/2026

Shelf Life: 24 Months Sampling Date: 07.09.2024 Report Date: 08.07.2024

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 ± 3.0% (208.6 to 221.5 mg)	206.1 mg
Uniformity of Weight	Not more than two tablets deviate from ± 7.5% and none deviates from ± 15% of average weight	Complies
Disintegration Test	NMT 30 Minutes	5:28 Minutes
Assay: Each film coated tablet contains: 24 mg Sacubitril and 26 mg Valsartan as Sodium salt complex	45.00 mg to 55.00 mg 90.00% to 110.00%	49.9219 mg 99.84%

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

Analysed by:

Date:

Checked by:

Date:

Approved by:

Date: