



UNITED BIOCEUTICALS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

Product Name: **DABIBROOK-110**

Test SPC No.: **UB/QC/STP3250**

Generic Name: Dabigatran Etxilate Mesylate Capsules 110 mg

Marketed by: Healing Pharma.

Mfg. Lic No.: 94/UA/2017

Batch No.: **C240004**

Batch Size: 51,000 Caps

Pack Size : 10 x 10's

A. R. No.: FPC24250023

Sample Quantity: 60 Caps

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	White to off white coloured powder filled in hard gelatin capsules having scarlet/scarlet cap & body.	Off white coloured powder filled in hard gelatin capsules having scarlet/scarlet cap & body.
Identification	By UV	Complies
Average Weight	295.0 mg $\pm$ 5.0% (280.3 to 309.8 mg)	291.1 mg
Average fill Weight	230.0 mg $\pm$ 5.0% (218.5 to 241.5 mg)	231.3 mg
Uniformity of Weight	Not more than two capsules deviates from $\pm$ 10 % and none deviates from $\pm$ 20% of Average Weight	Complies
Disintegration Test	NMT 30 Minutes	8:11 Minutes
Assay: Each hard gelatin capsule contains: Dabigatran Etxilate Mesylate 126.83 mg Eq. to Dabigatran Etxilate 110 mg	99.00 mg to 121.00 mg 90.00% to 110.00%	109.69 mg 99.72%

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

Analysed by:
Date:

Checked by:
Date:

Approved by:
Date: