



UNITED BIOCEUTICALS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

Product Name: Dabibrook-150		Test SPC No.: UB/QC/STP3353
Generic Name: Dabigatran Etxilate Mesylate Capsules 150 mg		
Marketed by: Healing Pharma		
Mfg. Lic No.: 94/UA/2017		Batch No.: C240205
Batch Size: 55,000 Caps	Pack Size: 10 x 10's	A. R. No.: FPC24250203
Sample Quantity: 60 Caps	Mfg. Date: 11/2024	Expiry Date: 10/2026
Shelf Life: 24 Months	Sampling Date: 15.11.2024	Report Date: 16.11.2024

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)	298.8 mg
Average fill Weight	230.0 mg $\pm$ 5.0% (218.5 to 241.5 mg)	233.8 mg
Uniformity of Weight	Not more than two capsules deviate from $\pm$ 10 % and none deviates from $\pm$ 20% of average weight	Complies
Disintegration Test	NMT 30 Minutes	7:12 Minutes
Assay: Each hard gelatin capsule contains: Dabigatran Etxilate Mesylate 172.95 mg Eq. to Dabigatran Etxilate 150 mg	135.00 mg to 165.00 mg 90.00% to 110.00%	149.48 mg 99.65%

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

Analysed by:
Date:

Checked by:
Date:

Approved by:
Date: