



IBN HERBALS
(A Unit of Curetech Formulations (P) Ltd.)

Khasra no.63, Village-Juddi Kalan, Baddi-173205 (H.P.)

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	RABIACE-DSR	A.R. No	IBNFP- 1006/24
Generic Name	Enteric Coated Rabeprazole and Domperidone Sustained Release Capsules	Batch No.	IHPI24065
Mfg. Date	JUN.2024	Exp. Date	MAY 2026
Receiving Date	09.07.2024	Released Date	15.07.2024
Batch Size	5.0 LAC.	Sample Qty.	60 CAPS

TEST	SPECIFICATION	RESULTS
Description:	Pink coloured cap and transparent body hard gelatin capsule filled with orange and brown coloured pellets.	Pink coloured cap and transparent body hard gelatin capsule filled with orange and brown coloured pellets.
Identification:	Should Comply	+ve for Rabeprazole Sodium and Domperidone
Average weight:	0.3400 g $\pm$ 5% [NLT 0.3230 gm , NMT 0.3570 gm]	0.3406 gm.
Average fill weight:	0.2750 gm $\pm$ 5 % (Limit: Min: 0.2613 gm, Max:0.2888 gm)	0.2773 gm.
Uniformity of Fill weight	Not more than two of the individual Capsule weights deviate from the average weight by more than $\pm 10.0\%$ none deviate more than $\pm 20.0\%$	Min: -2.08 % Max: +2.58 %
Dissolution:		
A) Rabeprazole	(1) In Acid Medium (NMT 10.0%) (2) In Buffer Medium (NLT 70.0%)	Min: 2.57 % Max: 4.34 % Min: 98.20% Max: 99.70 %
B) Domperidone	1 st hour (15 % to 45 %) 4 th hour (30 % to 65 %) 8 th hour (55 % to 85 %) 12 th hour (NLT 70 %)	Min: 29.8 % Max: 30.0 % Min: 48.7% Max: 49.9 % Min: 69.9 % Max: 72.4 % Min: 99.0% Max: 101.1 %

Assay:

Each Hard gelatin capsule contains:

	Limit (%)	Result (mg)	(%)
Rabeprazole Sodium IP..... 20mg (as enteric coated pellets)	Between 90.0 % to 110.0 %	20.87 mg	104.4 %
Domperidone IP..... 30mg (as sustained release pellets)	Between 90.0 % to 110.0 %	29.10 mg	97.0%

Remark: In the opinion of the under signed, above sample complies as per In House Specifications.

Prepared By	Checked by	Approved By
Date 15.07.2024	Date 15.07.2024	Date 15.07.2024