

**IBN HERBALS**

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

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

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

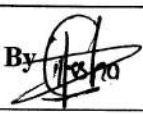
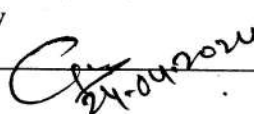
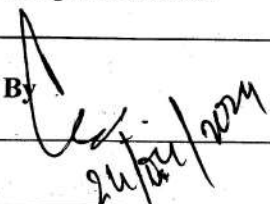
<b>Product Name</b>	<b>RABIACE-DSR</b>	<b>A.R. No</b>	IBNFP-0580/24
<b>Generic Name</b>	Enteric Coated Rabeprazole and Domperidone (Sustained Release) Capsules	<b>Batch No.</b>	IHPI24025
<b>Mfg. Date</b>	APR.2024	<b>Exp. Date</b>	MAR.2026
<b>Receiving Date</b>	20.04.2024	<b>Released Date</b>	24.04.2024
<b>Batch Size</b>	10.0 LAC.	<b>Sample Qty.</b>	60 CAPS

TEST	SPECIFICATION	RESULTS	
<b>Description:</b>	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.	
<b>Identification:</b>	Should Comply	+ve for Rabeprazole Sodium and Domperidone	
<b>Average weight:</b>	0.3400 g ± 5% [NLT 0.3230 gm , NMT 0.3570 gm]	0.3395 gm.	
<b>Average fill weight:</b>	0.2750 gm ± 5 % (Limit: Min: 0.2613 gm, Max:0.2888 gm)	0.2764 gm.	
<b>Uniformity of Fill weight</b>	Not more than two of the individual Capsule weights deviate from the average weight by more than ±10.0% none deviate more than ±20.0%	Min: -1.83 % Max: +1.68 %	
<b>Dissolution:</b>			
<b>A) Rabeprazole</b>	(1) In Acid Medium (NMT 10.0%)	Min: 2.28 %	Max: 4.10 %
	(2) In Buffer Medium (NLT 70.0%)	Min: 96.80%	Max: 98.90 %
<b>B) Domperidone</b>	1 <sup>st</sup> hour (15 % to 45 %)	Min: 26.7 %	Max: 36.7 %
	4 <sup>th</sup> hour (30 % to 65 %)	Min: 51.0%	Max: 60.1 %
	8 <sup>th</sup> hour (55 % to 85 %)	Min: 66.8 %	Max: 83.3 %
	12 <sup>th</sup> hour (NLT 70 %)	Min: 90.1 %	Max: 107.5 %

**Assay:**

Each Hard gelatin capsule contains:	Limit (%)	Result (mg)	(%)
Rabeprazole Sodium IP..... 20mg (as enteric coated pellets)	Between 90.0 % to 110.0 %	20.82 mg	104.1 %
Domperidone IP..... 30mg (as sustained release pellets)	Between 90.0 % to 110.0 %	29.26 mg	97.5%

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

<b>Prepared By</b> 	<b>Checked by</b> 	<b>Approved By</b> 
<b>Date</b> 24.04.2024	<b>Date</b> 24-04-2024	<b>Date</b> 24/04/2024