



DEN MARK PHARMACEUTICALS PVT. LTD.
PLOT # 112-A, HPSIDC INDUSTRIAL ESTATE DAVNI,
TEHSIL BADDI, DISTT. SOLAN (H.P.) 173205

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Product Name	Rabezcan - DSR Capsule				
Generic Name	Rabeprazole Sodium (Gastro Resistant) & Domperidone (Sustained Release) Capsule				
Batch No.	SC2394	A. R. No.	FP/22/480		
Batch Size	3,00,000 Lac	Mfg. Date	Oct.2022	Exp. Date	Sep. 2024
Qty. Sampled	100 Capsule	Analysis Date	10/10/2022	Release Date	12/10/2022

Sr. No	TEST		RESULT	SPECIFICATION
01	Description		Pink coloured cap and transparent body hard gelatin "2" size unprinted capsules containing orange and brown coloured pellets	Should be Pink coloured cap and transparent body hard gelatin "2" size unprinted capsules containing orange and brown coloured pellets.
02	Identification		Positive for Rabeprazole Sodium & Domperidone	Should be Positive for Rabeprazole Sodium & Domperidone
03	Average Weight		0.33916 gm.	0.339 gm. ± 3%
04	Average Net Weight		0.27683 gm.	0.275 gm. ± 3%
05	Uniformity of weight		Min.0.24930gm. Max.0.30470gm.	± 10 % of average fill weight
06	Uniformity of Locking Length		Min. 17.50 mm Max. 17.60 mm	NLT-17.30mm & NMT-17.80mm
07	Loss on Drying		3.70% w/w	NMT- 5.0% w/w
08	Disintegration Time		9 min.	NMT - 30 min
09	Dissolution			
	Rabeprazole Sodium	Acid Stage	Min. 1.55% Max. 3.50% Mean. 2.52%	NMT- 10% of the state amount of the Rabeprazole Sodium.
		Buffer Stage	Min.80.20% Max. 84.25% Mean. 82.22%	NLT- 75.0% of the state amount of the Rabeprazole.
	Domperidone		Min.25.9% Max. 29.56% Mean. 27.73%	After 1 Hours (15.0 to 40.0%)
			Min.44.0% Max.48.20% Mean. 46.10%	After 4 Hours (30.0 to 60.0%)
		Min. 65.3% Max. 70.25% Mean. 67.77%	After 8 Hours (55.0 to 85.0%)	
		Min. 80.65% Max. 85.23% Mean. 82.94%	After 12 Hours (NLT- 70%)	
10	Assay: - Each Hard Gelatin Capsule Contains :-			
	Rabeprazole Sodium IP 20 mg		19.90 mg (i.e. 99.51%)	NLT- 18.0 mg to NMT- 22.0 mg (90.0% to 110.0%)
	Domperidone IP 30.0 mg		29.55 mg (i.e. 98.49%)	NLT- 27.0 mg to NMT- 33.0 mg (90.0% to 110.0%)

Remarks: The above sample is Complies/~~Not Complies~~ with prescribed standard of quality as per IP/DP/USP/IHS.

	Prepared By	Checked BY	Approved By
Name	Rahul Thakur	Amit Kumar	Rakesh Singh
Designation	Q.C officer	Q.C Executive	Q.C. Manager
Sign./Date	Rahul Thakur 12/10/22	Amit 12/10/22	Rakesh Singh 12/10/22

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