



Kentreck Laboratories Pvt. Ltd.

56, AJANTA INDUSTRIAL ESTATE., P.O VASNA IYAVA, SANAND-382170
REG.OFF.: ADMIN OFF- 207 , ANAND MANGAL COMPLEX,, BH.OMKAR HOUSE, C.G.ROAD,, NAVRANGPURA,, AHMEDABAD-380001
C.I.No. : U24231GJ1989PTC012216

QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : RABEZCAN DSR CAPSULES	A.R. No. : KLFG240557
Packing : 10x10 CAP	Rel. Dt. : 25-01-2025
Generic Name : ENTERIC COATED RABEPRAZOLE SODIUM & DOMPERIDONE SR CAPSULES	T.R. Slip No. : KLFG240557
Product Code : RABE05	T.R. Slip Dt. : 25-01-2025
Batch No. : KN341	Analysis Date : 25-01-2025
Actual Batch Size : 159925 CAP (1599 BOX)	Specification No. : SP/FG/RABE05
Packing Batch Size : 59925 CAP	Specification Dt : 25-11-2024
Sample Size : 100.000 CAP	STP No. : SOP/003
Released Qty : 59925.000 CAP (599 BOX)	Location : SANAND
Remarks :	Make : KLPL
	Test As Per : IHS

Sr.	Test	Result	Specification
1	DESCRIPTION	Pink / Colourless transparent hard gelatin capsule contains multi colour pellets.	Pink / Colourless transparent hard gelatin capsule contains multi colour pellets.
2	UNIFORMITY OF WEIGHT	Weight of 20 capsules: 7.246 gm Avg. Wt. of capsules : 362.3 mg Avg. Wt of empty capsule: 63.5 mg Net Contain: 298.8 mg	Weight of 20 capsules: About 7.260 gm Avg. Wt. of capsules : About 363.0 mg Avg. Wt of empty capsule : About 63.0 mg Net Contain : About 300.0 mg (± 7.5 %)
3	GASTRIC RESISTANCE FOR RABEPRAZOLE SODIUM	Complies Mean - 1.42 %	NMT 15 % (0.1 M HCl)
4	DISSOLUTION	Complies Mean - 88.79 %	Rabeprazole Sodium NLT 70.0 %
5	DISSOLUTION (DOMPERIDONE) IN 900ML 0.1M HCL	Complies Hours % 1 27.74 % 4 42.34 % 8 71.37 % 12 86.76 %	Hours % 1 15 % to 40 % 4 30 % to 60 % 8 55 % to 85 % 12 NLT 70 %
6	ASSAY	1) 98.43 % 2) 100.12 %	Each capsule Contains : 1) Rabeprazole Sodium - 20 mg [Limit : Bet'n 90% to 110%] 2) Domperidone- 30 mg [Limit : Bet'n 90% to 110%]
7	PACKING STYLE	Complies	Alu-Alu Packing 10 X 10 Capsules

Conclusion : The above sample complies as per IHS
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By

Q.A./Q.C. Incharge