

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-380009
 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 Packing : 10x10 CAP Generic Name : ENTERIC COATED RABEPRAZOLE SODIUM & DOMPERIDONE SR CAPSULES Product Code : RABE05 Mfg. Dt. : 11/2024 Batch No. : KN266 Exp. Dt. : 10/2026 Actual Batch Size : 10000CAP (1000 BOX) Test Packing : 100 CAP Packing Batch Size : 50000 CAP Sample Size : 100.000 CAP Released Qty : 50000.000 CAP (500 BOX) Test As Per : IHS Remarks :	A.R. No. : KLFG240432 Rel. Dt. : 25-11-2024 T.R. Slip No. : KLFG240432 T.R. Slip Dt. : 25-11-2024 Analysis Date : 25-11-2024 Specification No. : SP/FG/RABE05 Specification Dt : 25-11-2024 STP No. : SOP/003 Location : SANAND Make : KLPL
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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: 7.296 gm Avg. Wt. of capsules: 364.8 mg Avg. Wt of empty capsule: 62.1 mg Net Contain: 302.7 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 - 1.43 %	NMT 15 % (0.1 M HCl)																				
4	DISSOLUTION	Complies Mean - 89.96 %	Rabeprazole Sodium NLT 70.0 %																				
5	DISSOLUTION (DOMPERIDONE) IN 900ML 0.1M HCL	Complies <table style="margin-left: 20px; border-collapse: collapse;"> <tr> <td>Hours</td> <td>%</td> </tr> <tr> <td>1</td> <td>23.15 %</td> </tr> <tr> <td>4</td> <td>43.66 %</td> </tr> <tr> <td>8</td> <td>74.82 %</td> </tr> <tr> <td>12</td> <td>91.85 %</td> </tr> </table>	Hours	%	1	23.15 %	4	43.66 %	8	74.82 %	12	91.85 %	<table style="margin-left: 20px; border-collapse: collapse;"> <tr> <td>Hours</td> <td>%</td> </tr> <tr> <td>1</td> <td>15 % to 40 %</td> </tr> <tr> <td>4</td> <td>30 % to 60 %</td> </tr> <tr> <td>8</td> <td>55 % to 85 %</td> </tr> <tr> <td>12</td> <td>NLT 70 %</td> </tr> </table>	Hours	%	1	15 % to 40 %	4	30 % to 60 %	8	55 % to 85 %	12	NLT 70 %
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6	ASSAY	1) 98.40 % 2) 100.21 %	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