



Finished Product Certificate of Analysis

Generic Name	Rifampicin Capsules BP 300mg	Analytical Report No.	KPL1/QC/AR/FP/25/3681
Product Name	Rifampicin Capsules 300mg	Reference Pharmacopoeia	BP
Batch No.	GC435	Batch Size	105000 CAPSULES
Mfg. Date	January 2025	Exp. Date	December 2027
Sample Received on	10/02/2025	Specification No	KPA/SLS/QC/109/2966
Analysis Initiated on	10/02/2025	Date of Release	21/02/2025

Analytical Data

Packing Presentation: 1 X 10 CAPSULES PACKED IN BLISTER STRIP.

S.No.	Tests	Specifications	Observations								
1	Description	Red color body and cap hard gelatin capsule of size '0' filled with brick red colored powder packed in blister strip.	Red color body and cap hard gelatin capsule of size '0' filled with brick red colored powder packed in blister strip.								
2	Identification										
	A Infrared absorption spectrum	Compare the spectrum with that obtained with Rifampicin RS/WS or with the reference spectrum of Rifampicin.	Identified								
	B UV spectrophotometer	The assay exhibits four maxima at 237, 254, 334 and 475 nm.	Identified								
3	Average fill weight	550 mg \pm 7.5 percent	560.36 mg								
4	Uniformity of fill capsules	\pm 7.5 percent of average fill weight	-1.94%, +0.98%								
5	Disintegration test	Not more than 30 minutes	07 minutes.								
6	Dissolution	Not less than 70% of the labeled amount of Rifampicin dissolved in 45 minutes.	1)81.4%, 2)81.0% 3)82.6%, 4)82.4% 5)82.6%, 6)91.9%								
7	Related substances	The area of any peak corresponding to rifampicin quinone: Not greater than 4% The area of any peak corresponding to rifampicin N-oxide: Not greater than 1.5% The area of any peak corresponding to 3-formylrifamycin SV: Not greater than 0.5% The area of any other secondary peak: Not greater than 1%	2.962% Not detected Not detected 0.332%								
8	Uniformity of dosage units	L1 = Maximum allowable acceptance value is not more than 15	6.2								
9	Microbial limits	Total Aerobic Microbial Count (TAMC): Not more than 1000 cfu/g Total yeast and mould count (TYMC): Not more than 100 cfu/g Escherichia coli: Should be absent/gm	20 cfu/g. <10 cfu/g. Absent								
10	Assay	<table><tr><th>Limit</th><th>Claim</th><th>Result</th><th>%age</th></tr><tr><td>92.5% - 107.5%</td><td>300 mg</td><td>286.0 mg</td><td>95.3%</td></tr></table>	Limit	Claim	Result	%age	92.5% - 107.5%	300 mg	286.0 mg	95.3%	
Limit	Claim	Result	%age								
92.5% - 107.5%	300 mg	286.0 mg	95.3%								

Conclusion : The above product complies with above specifications and meets the standard quality as per BP.

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