



INNOVA CAPTAB LTD
1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I,
JHARMAJRI, BADDI (HP) INDIA

Certificate of Analysis

Product Name: Rosufree - Gold 10

Generic Name	Rosuvastatin, Aspirin & Clopidogrel Capsules	Packing Code	G6110007
Batch Log No	32413411	Packing Batch No	G6114006
Bulk Batch No	G6114006	Batch Size	3.0 Lac
Packing Type	(10x10) Capsules	Date of Analysis	07/04/2024
A.R. No.	2003FP324001715	Reference	IN HOUSE
Mfg. Date	04/2024	Exp. Date	03/2026
Specification No	FPS-G611-05	Date of Release	19/04/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Pink coloured cap and Clear Transparent coloured body Size"1" hard gelatin capsule containing white to off white, Blue coloured and sunset yellow coloured spherical pellets.	Pink coloured cap and Clear Transparent coloured body Size"1" hard gelatin capsule containing white, Blue coloured and sunset yellow coloured spherical pellets.
2	Identification		
2.1	For Aspirin	Scan the standard solution and test solution, as prepared for Assay estimation, between 220 nm and 350nm. Both should have same maxima.	Scan the standard solution and test solution, as prepared for Assay estimation, between 220 nm and 350nm. Both should have same maxima.
2.2	For Clopidogrel	Scan the standard solution and test solution, as prepared for Assay estimation, between 220 nm and 350nm. Both should have same maxima.	Scan the standard solution and test solution, as prepared for Assay estimation, between 220 nm and 350nm. Both should have same maxima.
2.3	For Rosuvastatin	Scan the standard solution and test solution, as prepared for Assay estimation, between 220 nm and 350nm. Both should have same maxima.	Scan the standard solution and test solution, as prepared for Assay estimation, between 220 nm and 350nm. Both should have same maxima.
3	Average weight of filled capsule	436.0mg $\pm$ 7.5%	436.4 mg
4	Average net content of capsule	360.0mg $\pm$ 7.5%	357.6 mg
5	Uniformity of weight	$\pm$ 7.5% of Average weight	%Maximum +ve deviation : 2.4 % %Maximum -ve deviation:-2.4 %
6	Moisture content	Not more than 3.0%	1.17 %
7	Dissolution-Asprin		
7.1	Acid Stage	Not more than 10.0% of the label claim.	Min : 2.6 % Max : 2.9 %

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By		Reviewed By	Approved By
rahul.kumar(Chemist)		omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
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			Avg:2.7 %
7.2	Buffer stage	Not less than 70.0% of label claim.	Min : 99.8 % Max : 100.8 % Avg:100.2 %
8	Dissolution		
8.1	Rosuvastatin	Not less than 70.0% of labeled amount of Rosuvastatin calcium should be dissolved in buffer solution pH 6.8 at 30 minutes.	Min : 95.8 % Max : 97.0 % Avg:96.5 %
9	Assay-Each hard gelatin capsule contains:		
9.1	Rosuvastatin Calcium IP Equivalent to Rosuvastatin.....10mg (As pellets)	9.00mg to 11.00mg (90.0% to 110.0% of the Labeled claim)	Assay (i) % : 104.8 % Assay: mg/Cap:10.48 mg/Cap
9.2	Clopidogrel Bisulphate IP Equivalent to Clopidogrel..... 75mg (As pellets)	67.50mg to 82.50mg (90.0% to 110.0% of Labeled claim)	Assay (i) % : 98.6 % Assay: mg/cap:73.99 mg/Cap
9.3	Aspirin IP.....75mg (As enteric coated pellets)	67.50mg to 82.50mg (90.0% to 110.0% of the Labeled claim)	Assay (i) % : 101.3 % Assay: mg/cap:75.95 mg/Cap

Remarks: APPROVED (Sample conforms to above Specification)

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