



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

Certificate of Analysis

Product Name: Rosufree - Gold-20

Generic Name	Rosuvastatin, Clopidogrel & Aspirin Capsules	Packing Code	G6120006
Batch Log No	32421601	Packing Batch No	G6124006
Bulk Batch No	G6124006	Batch Size	3.0 Lac
Packing Type	(10x10 Caps)	Date of Analysis	27/05/2024
A.R. No.	2003FP324002600	Reference	IN HOUSE
Mfg. Date	05/2024	Exp. Date	04/2026
Specification No	FPS-G612-04	Date of Release	12/06/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Red 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.	Red 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%	436.3 mg
4	Average net content of capsule	360.0mg $\pm$ 7.5%	359.9 mg
5	Uniformity of weight	$\pm$ 7.5% of Average weight	%Maximum +ve deviation : 2.4 % %Maximum -ve deviation:-3.0 %
6	Moisture content	Not more than 3.0%	1.11 %
7	Dissolution-Asprin		
7.1	Asprin_Acid Stage	Not more than 10.0% of the label claim.	Min : 0.9 % Max : 2.2 % Avg:1.7 %
7.2	Buffer stage	Not less than 70.0% of label claim.	Min : 99.2 % Max : 101.3 %

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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8	Dissolution		Avg:100.0 %
8.1	Rosuvastatin	Not less than 70.0% of labeled amount of Rosuvastatin should be dissolved in buffer solution pH 6.8 at 30 minutes.	Min : 90.9 % Max : 91.6 % Avg:91.2 %
9	Assay-Each hard gelatin capsule contains:		
9.1	Rosuvastatin Calcium IP Equivalent to Rosuvastatin.....20mg (As pellets)	18.00mg to 22.00mg (90.0% to 110.0% of the Labeled claim)	Assay (i) % : 100.3 % Assay: mg/Cap:20.05 mg/Cap
9.2	Aspirin IP.....75mg (As enteric coated pellets)	67.50mg to 82.50mg (90.0% to 110.0% of the Labeled claim)	Assay (i) % : 101.9 % Assay: mg/cap:76.44 mg/Cap
9.3	Clopidogrel Bisulphate IP Equivalent to Clopidogrel.....75mg (As pellets)	67.50mg to 82.50mg (90.0% to 110.0% of Labeled claim)	Assay (i) % : 108.2 % Assay: mg/cap:81.11 mg/Cap

Remarks: APPROVED (Sample conforms to above Specification)

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