



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

Certificate of Analysis

Product Name: Rosufree CV 10/75

Generic Name	Rosuvastatin & Clopidogrel Capsules	Packing Code	G6104004
Batch Log No	32426882	Packing Batch No	G6104004
Bulk Batch No	G6104004	Batch Size	2.0 Lac
Packing Type	(10x10) Capsules	Date of Analysis	02/07/2024
A.R. No.	2003FP324003299	Reference	IN HOUSE
Mfg. Date	06/2024	Exp. Date	05/2026
Specification No	FPS-G610-01	Date of Release	13/09/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Red coloured cap and white coloured body Size "2" hard gelatin capsule containing blue and orange coloured spherical pellets.	Red coloured cap and white coloured body Size "2" hard gelatin capsule containing blue and orange coloured spherical pellets.
2	Identification (BY HPLC)	In the assay, the retention time of the major peaks in the chromatogram of the sample preparation corresponds to that of the standard preparation.	In the assay, the retention time of the major peaks in the chromatogram of the sample preparation corresponds to that of the standard preparation.
3	Average weight of filled capsule	343.0mg $\pm$ 7.5%	331.8 mg
4	Average net content of capsule	278.0mg $\pm$ 10.0%	273.5 mg
5	Uniformity of weight	$\pm$ 10.0% of Avg. wt.	%Maximum +ve deviation : 2.5 % %Maximum -ve deviation:-3.4 %
6	Rosuvastatin	Not less than 65.0% (Q) of labeled amount should be dissolve in phosphate buffer pH 6.8 in 60 minutes.	Min : 97.8 % Max : 113.9 % Avg:104.3 %
7	Clopidogrel	Not less than 65.0% (Q) of labeled amount should be dissolve in 0.1M Hydrochloric acid in 60 minutes.	Min : 101.0 % Max : 105.6 % Avg:104.1 %
8	Assay-Each hard gelatin capsule contains:		
8.1	Rosuvastatin Calcium IP Equivalent to Rosuvastatin..... 10mg (As Pellets)	9.00mg to 11.00mg (90.0% to 110.0% of Labeled claim)	Assay % of Label Claim: : 104.2 % Assay: mg/cap:10.42 mg/Cap
8.2	Clopidogrel Bisulphate IP Equivalent to Clopidogrel.....	67.50mg to 82.50mg (90.0% to 110.0% of Labeled claim)	Assay % of Label Claim: :

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By	Reviewed By	Approved By
rahul.kumar(Chemist)	omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
13/09/2024 10:10	13/09/2024 12:35	13/09/2024 13:16
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S. No.	TEST	SPECIFICATION	RESULT
	75mg (As Pellets)		102.2 % Assay: mg/cap:76.63 mg/cap

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By rahul.kumar(Chemist) 13/09/2024 10:10	Reviewed By omprakash.sharma(Manager) 13/09/2024 12:35	Approved By Mahendra.Bisht(Manager) 13/09/2024 13:16
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