



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

Certificate of Analysis

Product Name: Rosufree CV 20/75

Generic Name	Rosuvastatin & Clopidogrel Capsules	Packing Code	G5860004
Batch Log No	32435171	Packing Batch No	G5864002
Bulk Batch No	G5864002	Batch Size	4.0 Lac
Packing Type	(10x10) Capsules	Date of Analysis	02/09/2024
A.R. No.	2003FP324004357	Reference	IN HOUSE
Mfg. Date	08/2024	Exp. Date	07/2026
Specification No	FPS-G586-03	Date of Release	11/09/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Size '2' hard gelatin capsules dark blue cap and white colour body containing blue and orange colored spherical pellets.	Size '2' hard gelatin capsules dark blue cap and white colour body containing blue and orange colored 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%	343.6 mg
4	Average net content of capsule	278.0mg $\pm$ 10.0%	280.4 mg
5	Uniformity of weight	$\pm$ 10.0% of Avg. wt.	%Maximum +ve deviation : 1.3 % %Maximum -ve deviation:-1.5 %
6	Dissolution		
6.1	Rosuvastatin	Not less than 65.0% (Q) of labeled amount should be dissolve in phosphate buffer pH 6.8 in 60 minutes.	Min : 99.3 % Max : 99.5 % Avg:99.4 %
6.2	Clopidogrel	Not less than 65.0% (Q) of labeled amount should be dissolve in 0.1M Hydrochloric acid in 60 minutes.	Min : 99.9 % Max : 107.0 % Avg:102.8 %
7	Assay-Each hard gelatin capsule contains:		
7.1	Rosuvastatin Calcium IP Equivalent to Rosuvastatin..... 20mg (As Pellets)	18.00mg to 22.00mg (90.0% to 110.0% of Labeled claim)	Assay % of Label Claim: : 100.5 % Assay: mg/cap:20.11 mg/Cap

Remarks: APPROVED (Sample conforms to above Specification)

Approved

Prepared By		Reviewed By	Approved By
rahul.kumar(Chemist)		omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
11/09/2024 11:39		11/09/2024 11:53	11/09/2024 14:48
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S. No.	TEST	SPECIFICATION	RESULT
7.2	Clopidogrel Bisulphate IP Equivalent to Clopidogrel..... 75mg (As Pellets)	67.50mg to 82.50mg (90.0% to 110.0% of Labeled claim)	Assay % of Label Claim: : 99.2 % Assay: mg/cap:74.41 mg/cap
8	Additional Tests		
8.1	Moisture content	Not more than 5.0%	2.41 %

Remarks: APPROVED (Sample conforms to above Specification)

Approved

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rahul.kumar(Chemist)		omprakash.sharma(Manager)		Mahendra.Bisht(Manager)	
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