



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

Certificate of Analysis

Product Name: Lipidator Gold 20

Generic Name	Atorvastatin, Clopidogrel and Aspirin Capsules	Packing Code	G6190007
Batch Log No	32426313	Packing Batch No	G6194006
Bulk Batch No	G6194006	Batch Size	2.0 Lac
Packing Type	(10x10) Capsules	Date of Analysis	20/06/2024
A.R. No.	2003FP324003074	Reference	IN HOUSE
Mfg. Date	06/2024	Exp. Date	05/2026
Specification No	FPS-G619-00	Date of Release	03/07/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Size '1' hard gelatin capsules Green cap and White color body containing white to off white, orange and green colored spherical pellets.	Size '1' hard gelatin capsules Green cap and White color body containing white, orange and green colored spherical pellets.
2	Identification		
2.1	For Aspirin	Positive for Aspirin	Positive for Aspirin
2.2	For Clopidogrel	Positive for Clopidogrel	Positive for Clopidogrel
2.3	For Atorvastatin	Positive for Atorvastatin	Positive for Atorvastatin
3	Average weight of filled capsule	436.0mg $\pm$ 7.5%	435.9 mg
4	Average net content of capsule	360.0mg $\pm$ 7.5%	357.7 mg
5	Uniformity of weight	$\pm$ 7.5% of Average weight	%Maximum +ve deviation : 1.7 % %Maximum -ve deviation:-2.8 %
6	Dissolution-Asprin		
6.1	Acid Stage	Not less than 85.0% of label claim, the drug should retain as residue in 0.1N HCl at 100 RPM after 1 hour.	Min. : 100.1 % Max. : 101.1 % Avg.:100.5 %
6.2	Buffer stage	Not less than 70.0% of label claim, the drug should dissolve in pH 6.8 phosphate buffer at 100 RPM after 45 minutes.	Min. : 90.5 % Max. : 91.4 % Avg.:91.0 %
7	Dissolution		
7.1	Clopidogrel	Not less than 80.0% of label claim, the drug should dissolve in 0.1N HCl at 50 RPM after 30 minutes.	Min. : 98.5 % Max. : 101.3 % Average::100.1 %
7.2	Atorvastatin	Not less than 70.0% of label claim, the drug should dissolve in pH 6.8 phosphate buffer at 75 RPM after 30 minutes.	Min. : 85.5 % Max. : 86.2 %

Remarks: APPROVED (Sample conforms to above Specification)

Approved

Prepared By		Reviewed By	Approved By
rahul.kumar(Chemist)		omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
03/07/2024 12:05		03/07/2024 12:09	03/07/2024 16:24
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8	Assay-Each hard gelatin capsule contains:		Avg.:85.9 %
8.1	Atorvastatin Calcium IP equivalent to Atorvastatin..... 20mg (as pellets)	18.00mg to 22.00mg (90.0% to 110.0% of the Labeled claim)	Assay (i) % : 93.8 % Assay: mg/Cap:18.75 mg/Cap
8.2	Clopidogrel Bisulphate IP equivalent to Clopidogrel..... 75 mg (as pellets)	67.50mg to 82.50mg (90.0% to 110.0% of Labeled claim)	Assay (i) % : 108.9 % Assay: mg/cap:81.69 mg/Cap
8.3	Aspirin IP.....75mg (as enteric coated pellets)	67.50mg to 82.50mg (90.0% to 110.0% of the Labeled claim)	Assay (i) % : 101.4 % Assay: mg/cap:76.06 mg/Cap

Remarks: APPROVED (Sample conforms to above Specification)

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