

Certificate of Analysis

Product Name: Lipidator Gold 10

Generic Name	Atorvastatin Clopidogrel and Aspirin Capsules	Packing Code	G6180007
Batch Log No	32452801	Packing Batch No	G6184010A
Bulk Batch No	G6184010	Batch Size	2.0 Lac
Packing Type	(10x10) Capsules	Date of Analysis	14/12/2024
A.R. No.	2003FP324006489	Reference	In-House
Mfg. Date	11/2024	Exp. Date	10/2026
Specification No	FPS-G618-00	Date of Release	21/12/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Size '1' hard gelatin capsules Blue cap and D. Yellow color body containing white to off white, orange and green colored spherical pellets.	Size '1' hard gelatin capsules Blue cap and D. Yellow 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%	437.9 mg
4	Average net content of capsule	360.0mg $\pm$ 7.5%	361.5 mg
5	Uniformity of weight	$\pm$ 7.5% of Average weight	%Maximum +ve deviation : 2.1 % %Maximum -ve deviation:-2.0 %
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. : 99.3 % Max. : 100.4 % Avg.:99.8 %
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. : 88.8 % Max. : 90.9 % Avg.:89.7 %
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: : 88.0 % Max: : 89.0 % Average::88.5 %
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. : 88.1 % Max. : 89.3 % Avg.:88.7 %

Remarks: APPROVED (Sample conforms to above Specification)

Comments: -

Prepared By		Reviewed By	Approved By
rahul.kumar(Chemist)		ramujagir.yadav(Chemist)	omprakash.sharma(Manager)
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JHARMAJRI, BADDI (HP) INDIA

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S. No.	TEST	SPECIFICATION	RESULT
8	Assay-Each hard gelatin capsule contains:		
8.1	Atorvastatin Calcium IP equivalent to Atorvastatin..... 10mg (as pellets)	9.00mg to 11.00mg (90.0% to 110.0% of the Labeled claim)	Assay (i) % : 101.2 % Assay: mg/Cap:10.12 mg/Cap
8.2	Clopidogrel Bisulphate IP equivalent to Clopidogrel..... 75mg (as pellets)	67.50mg to 82.50mg (90.0% to 110.0% of Labeled claim)	Assay (i) % : 101.2 % Assay: mg/cap:75.86 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) % : 102.4 % Assay: mg/cap:76.78 mg/Cap
9	Microbial Limit		
9.1	Total aerobic microbial count	Not more than 10^3 CFU/gm	20 CFU/gm
9.2	Total molds & yeasts count	Not more than 10^2 CFU/gm	<10 CFU/gm
9.3	E.coli	Absent /gm	Absent /gm

Remarks: APPROVED (Sample conforms to above Specification)

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