STALLION LABORATORIES PRIVATE LIMITED

(A Pharmaceutical formulation company)

Corporate Off. : 8th Floor, Devpath Complex, B/h Lal Bunglow, Off.C.G.Road, Ahmedabad, Gujarat.

PLOT NO. C1B-305,2,3,4,& 5, G.I.D.C., KERALA (BAVLA - 382220),Dist. Ahmedabad, Gujarat State, India

Phone : +91 (079) 26441993, 66040700. E-mail : info@stallionlabs.com Web : www.stallionlabs.com

CIN Number : U24231GJ1988PTC010285

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: TROVIPRI 40	**A.R. No.**	: TF/09/22/0935
		Rel. Dt.	: 29-10-2022
Packing	: 10x10 TAB	**T.R. Slip No.**	: SBABAFG/01/02042
Generic Name	: ATORVASTATIN TABLET USP 40 MG	**T.R. Slip Dt.**	: 17-09-2022
		Analysis Date	: 25-09-2022
Product Code	: TROV03	**Mfg. Lic. No.**	: G/898
Batch No.	: PH-1769	**Sample Size**	: 100.00 TAB
Actual Batch Size:	10,20,000.00 TAB	**Released Qty.**	: 10,20,000.00 TAB
Mfg. Dt. :	AUG-2022		
Exp. Dt. :	JUL-2025		
Test As per :	USP		
		Location	: BAVLA
		Company	: STALLION

Sr.	Test	Result	Specification
1.00	**Description**	White colour, round shaped, biconvex, film coated tablets having one side break line and other side plain.	White colour, round shaped, biconvex, film coated tablets having one side break line and other side plain.
2.01	**Identification A**	Complies (By UV)	The UV absorption spectrum of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.(Use diode array ; uv-200 – 400 nm)
2.02	**Identification B**	Complies (By HPLC)	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
3.00	**Average weight**	414.915 mg	412.00 mg ± 7.5 % (381.100 mg to 442.900 mg)
4.00	**Uniformity of weight**	Complies	± 7.5 % of Average weight
5.00	**Disintegration Time**	06 Minutes, 27 Seconds	NMT 30 Minutes
6.00	**Dissolution (By UV Visible Spectrophotometer)**	Complies (1) 91.71%, (2) 89.13%, (3) 88.14%, (4) 87.75%, (5) 88.93%, (6) 89.33%, Min : 87.75%, Max : 91.71%.	NLT 80% (Q) of the labeled amount of Atorvastatin is dissolved in 15 minutes.
7.00	**Assay (By HPLC).**	Label : 40.00 mg/tab Actual : 41.464 mg/tab Assay : 103.66%	94.5 % to 105.0 % of the labeled amount of Atorvastatin.
8.00	**Organic impurities (By HPLC)**	Not detected Not detected Not detected Not detected Not detected Not detected	Atorvastatin Pyrrolidone analogd : NMT 0.5% Atorvastatin related compound Hh : NMT 1.0% Atorvastatin epoxy pyrrolooxazin 6-hydroxy analogi : NMT 0.5% Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog, if present k : NMT 0.5% Atorvastatin epoxy THF analog I,m : NMT 1.0% Atorvastatin related compound Dn : NMT 0.5%

Prepared By	Checked By	Approved By
DILIP	BALKRUSHNA	AMRUT DARJI
OFFICER QC 29/10/22	ASST. QC MANAGER 29/10/22	ASST.GENERAL MANAGER 29/10/22

STALLION LABORATORIES PVT. LTD. 29/10/22

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Mfg. Dt. :	AUG-2022		
Exp. Dt. :	JUL-2025		
Test As per :	USP		
		Location	: BAVLA
		Company	: STALLION

Sr.	Test	Result	Specification
		Not detected Not detected	Any other unspecified degradation product : NMT 0.2% Total degradation products : NMT 4.0%
9.00	**Uniformity of content (By content uniformity)**	Acceptance value : 5.59	Acceptance value of 10 units ≤ 15.0 Acceptance value of 30 units ≤ 15.0 and no unit is less than [1- (0.01) (L-2)] M not more than [1+ (0.01) (L-2)] M L1= 15.0, L2=25.0
10.00	**Microbial limit**	10 cfu/gm < 10 cfu/gm Absent/gm	Total Aerobic Microbial Count [Limit : NMT 1000 cfu/gm] Total combined yeast/molds counts [Limit : NMT 100 cfu/gm] E.coli [Limit : Absent/gm]

Conclusion : The above sample complies as per USP

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