CERTIFICATE OF ANALYSIS

(Certificate No. KMA002078-01)

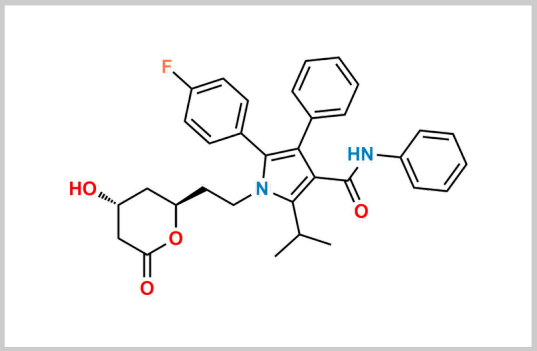
Release Date: 21/09/2024 **Re-test Date:** 20/09/2027

Atorvastatin EP Impurity H

Identification

Chemical Name :
(4R,6R)-6-[2-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]ethyl]-4-hydroxyoxan-2-one (as per EP); 5-(4-Fluorophenyl)-1-{2-[(2R, 4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl]ethyl}-2-isopropyl-N,4-diphenyl-1H-pyrrole-3-carboxamide (as per USP)

Alt. Name	: Atorvastatin USP related Compound H ; Atorvastatin lactone (USP) ; Atorvastatin δ-lactone
CAT No.	: KMA002078
CAS No.	: 125995-03-1
Molecular Formula	: C33H33FN2O4
Molecular Weight	: 540.6



Analytical Information

Batch No.	: ATS-LAC-011-120	**Solubility**	: DMF
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 95.18 %	**IR**	: Confirm
Weight Loss By TGA	: 0.46 %	**1H NMR**	: Confirm
% Potency	: 94.74 %		

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.46(Weight Loss By TGA)] x [95.18(HPLC Purity)]/100 = 94.74 %
-Re-tested on 21.09.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		21/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		21/09/2024

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA