

ASIA OFFICE: **Clearsynth Labs Ltd.** 17, Lotus Business Park,Off New Link Rd, Andheri (W),Mumbai - 400053 India Tel: +91.22.45045900 sales@clearsynth.com ASIA R&D CENTRE **Clearsynth Research Centre** Plot No. 177, IDA, Mallapur, Hyderabad-500076 Telangana, India T:+91-40.27.155481 NORTH AMERICAN R&D CENTRE Clearsynth Canada Inc. 118 Queen Street,Unit 202, Brampton, Ontario L6X 1A4, Canada Tel: +1.289.729.0060 Fax :- +1-289-729-0064

> Version No. 1.6 Date : --

Print Date :13/07/2022

Quality Accreditations : ISO 9001:2015 ISO 14001:2015 OHSAS 18001:2007 ISO 17034:2016 ISO/IEC 17025:2017 DSIR Recognition Only for R&D & Analytical purpose. Not meant for Human Consumption.

Product Name	(3S,5S)-Atorvastatin Calcium Salt	(3S,5S)-Atorvastatin Calcium Salt		
IUPAC Name	(3S,5S)-7-[3-(phenylcarbamoyl)-5- (4-fluorophenyl)-2-isopropyl-4-phenyl-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid, calcium salt			
Synonyms	Atorvastatin Related Compound E			
CAS #	1105067-88-6			
Catalog #	CS-T-48403 B	atch #	CRC-AAA-2654-01	
Molecular Formula	C <sub>66</sub> H <sub>68</sub> CaF <sub>2</sub> N <sub>4</sub> O <sub>10</sub>	olecular weight	1155.34	
Date of Analysis	13/07/2022 R	etest Date	13/07/2027	
Longterm Storage Conditions	Store at refrigerator (2-8°C) for long term storage	Store at refrigerator (2-8°C) for long term storage		
Shipping Conditions	Product is stable to be shipped at room tempera	Product is stable to be shipped at room temperature		
	OH OH O NH OH O	Ca <sup>2+</sup>		
Test	OH       OH <td< th=""><th>Ca<sup>2+</sup></th><th>Result</th></td<>	Ca <sup>2+</sup>	Result	
		2		
Appearance	OH       OH <td< td=""><td>Ca<sup>2+</sup> 2 Off white solid In DMSO</td><td></td></td<>	Ca <sup>2+</sup> 2 Off white solid In DMSO		
	White to off white solid	2 Off white solid		
Appearance Solubility	White to off white solid         Soluble in DMSO	2 Off white solid In DMSO		
Appearance Solubility Mass Spectrum	White to off white solid         Soluble in DMSO         Conform molecular weight	2 Off white solid In DMSO Confirms		
Appearance Solubility Mass Spectrum 1H NMR spectrum Purity by HPLC-c Volatiles content % (by TGA) - b	White to off white solid         Soluble in DMSO         Conform molecular weight         Conform Structure         Not less than 90%         Not specified	2 Off white solid In DMSO Confirms Confirms 96.27% 2.33% (w/w)		
Appearance Solubility Mass Spectrum 1H NMR spectrum Purity by HPLC-c	White to off white solid         Soluble in DMSO         Conform molecular weight         Conform Structure         Not less than 90%	2 Off white solid In DMSO Confirms Confirms 96.27%		

This Material Complies.

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13/07/2022 Reviewed & Approved by ( QC Analytical )

ams

13/07/2022 Reviewed & Approved by ( Quality Assurance )

All dates are mentioned in the format of DD/MM/YYYY

The re-test data is assigned based on the literature available. The balances used are calibrated with weights traceable to the National standards NIST. sales@clearsynth.com | www.clearsynth.com | Worldwide Helpline No:- +1(415) 685 -4395 | CIN :- U24100MH2010PLC201433

"The <u>'Catalyst'</u> in making your research work"

Empower2

## Injection Summary Report 01

CLEARSYNTH RESERCH CENTRE INST ID: HPLC-05

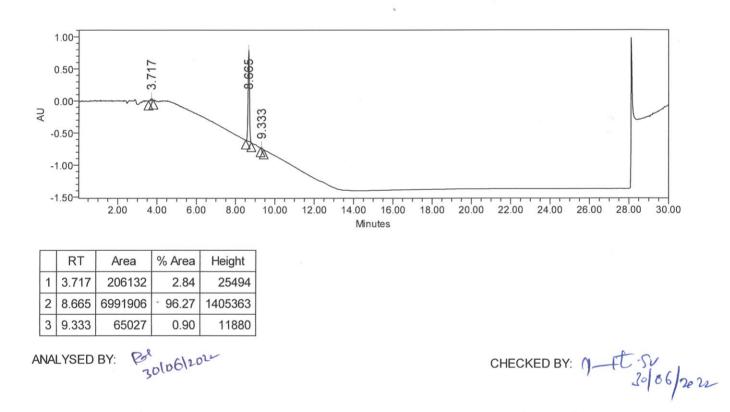
Sample Name:	CRC-AAA-2654-01	Acquired By:	Prabhakar
Sample Type:	Unknown	Sample Set Name:	29062022
Vial:	45	Acq. Method Set:	GENARAL METHOD 30MIN
Injection #:	1	Processing Method:	2654_01
Injection Volume:	5.00 ul	Channel Name:	200.0nm
Run Time:	30.0 Minutes	Proc. Chnl. Descr.:	PDA 200.0 nm
Date Acquired:	6/30/2022 2:29:38 AM IST	6 :	2
Date Processed:	6/30/2022 6:22:03 AM IST		4

SampleName: CRC-AAA-2654-01

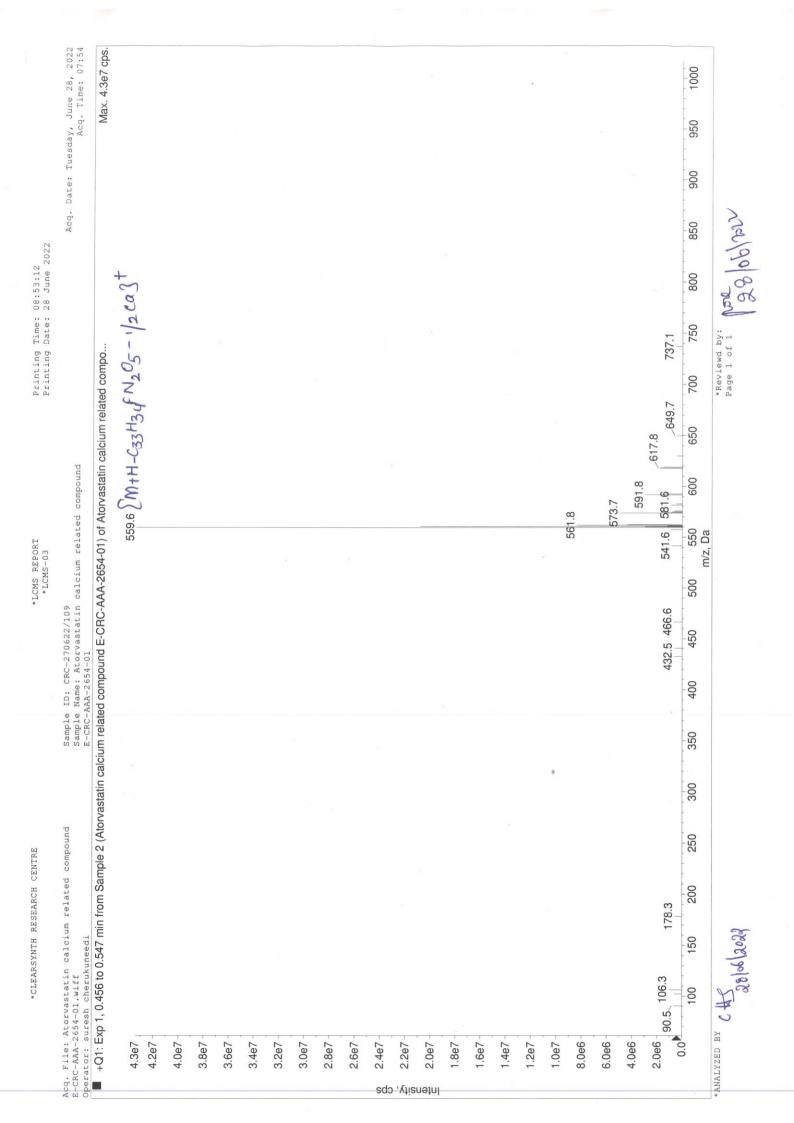
AR.no.: CRC-290622-109

MOA MP-A:10mM NH4OAC IN WATER:MP-B:ACN

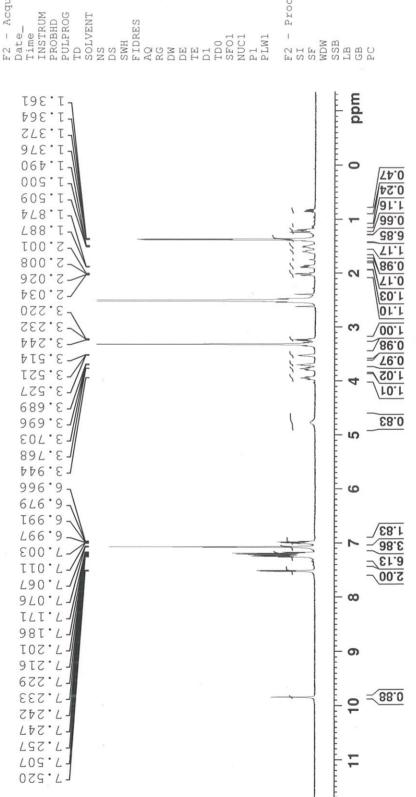
,T%B:0/10,10/90,25/9,25.1/10,30/10,FLOW:.1.0ML/MIN,Phenomenix-C18\*250\*4.6\*5µm (QC-COL-154)



Reported by User: P.RAKESH (rakeshp) Report Method: Injection Summary Report 01 Report Method ID: 7569 Page: 1 of 1 Project Name: JUNE-2022 Date Printed: 6/30/2022 6:39:00 AM Asia/Calcutta



CRC-AAA-2654-01 1H-NMR\DMSO CRC-270622/109





Clearsynth

41.600 usec 6.50 usec 301.6 K 1.00000000 sec 10.00 usec 25.92499924 W 12019.230 Hz 0.366798 Hz 2.7262976 sec 139.77 F2 - Acquisition Parameters 600.3037069 MHz 600.3000039 MHz F2 - Processing parameters
S1 600.300039 MHz 0.30 Hz 20220628 12.07 h zg30 DMSO 1 H 16 N EM Z114607\_0866 ( 65536 spect 0

30/06 2017 Reviewed By: JM

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Analysed By:

12019.230 Hz 0.366798 Hz 2.7262976 sec 139.77 41.600 usec 6.50 usec 301.6 K 1.0000000 sec 10.00 usec 25.92499924 W F2 - Acquisition Parameters Date\_ 20220628 600.3037069 MHz 600.3000039 MHz EM F2 - Processing parameters SI 65536 SF 600.3000039 MHz WDW EM 0.30 Hz 12.07 h Current Data Parameters NAME CRC-AAA-2654-01 Z114607\_0866 ( zg30 65536 1.00 16 1H spect DMSO 0 C PROBHD PULPROG INSTRUM SOLVENT EXPNO PROCNO FIDRES Date\_ Time TD0 SF01 NUC1 PLW1 DS SWH SSB GB PC ΠD ΤE D1 AQ DW DE NS P1 6.8 ppm 6.9 996 · 9 626 · 9 766 · 9 266 · 9 200 · 2 700 · 2 670 · 2 290 · 2 920 · 2 7.0 7.1 L:171 L:171 L:186 L:201 L:233 L:2335 L:2335 L:2335 L:2335 L:2335 L:2335 L:2335 L: 7.2 51.3 7.3 7.4 7.5 LOS'L 2.00 7.6 7.7

CRC-AAA-2654-01 1H-NMR\DMSO CRC-270622/109

Clearsynth

Reviewed By: Ht 3506

1.83

3.86

Analysed By: (M

30/06/2022

Clearsynth

Current Data Parameters

12019.230 Hz 0.366798 Hz 2.7262976 sec 139.77 41.600 usec 6.50 usec 301.6 K 1.0000000 sec 10.00 usec 25.92499924 W 600.3037069 MHz 600.3000039 MHz EM F2 - Acquisition Parameters F2 - Processing parameters' SI 65536 SF 600.3000039 MHz WDW EM SSB 0 20220628 20220628 12.07 h spect 2114607\_0866 ( 0.30 Hz CRC-AAA-2654-01 zg30 65536 1.00 16 1H DMSO C PROBHD PULPROG TD SOLVENT INSTRUM FIDRES PROCNO Date\_ EXPNO NAME Time TD0 SF01 NUC1 PLW1 NS DS SWH LB GB PC D1 P1 ppm 3.0 3.1 -3.198 -3.209 -3.220 -3.232 -3.232 -3.256 3.2 00. r 3.3 3.4 3.500 3.500 3.527 3.675 3.689 3.689 3.689 3.689 3.689 3.680 3.703 3.703 3.703 3.5 86.0 3.6 26.0 3.7 ₽₽L 192 92 92 98 56 226 926 596 696 3.8 1.02 3.9 10.1 4.0 4.1 4.2

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Analysed By: 🕅

30 06 2022

Clearsynth

Current Data Parameters NAME CRC-AAA-2654-01

12019.230 Hz 0.366798 Hz 2.7262976 sec 139.77 41.600 usec 6.50 usec 301.6 K 1.0000000 sec 25.92499924 W F2 - Acquisition Parameters Date\_\_\_\_20220628 600.3037069 MHz 600.3000039 MHz F2 - Processing parameters SI 65536 SF 600.3000039 MHz WDW EM HZ 12.07 h spect Z114607\_0866 ( zg30 65536 0.30 DMSO 1H 1.00 16 0 0 INSTRUM PULPROG SOLVENT PROCNO PROBHD FIDRES EXPNO Time SF01 NUC1 PLW1 HWS SSB GB PC TDO ΠD NS DS AQ DW DE TE D1 F1 mdd and an and an a 0.7 0.8 74.0 0.9 1.0 -1-121 -1-123 -1-123 1 0.24 91.1 2 т т т 361 364 372 376 469 490 99.0 1.3 28.9 τ • τ 1.4 • T 200 • T 1.5 71.1 203 230 249 284 269 250 272 τ τ 1.6 τ 86.0 τ τ 1.7 τ • 71.0 τ 1.8 846 895 ٠ ۲ • โ €20.2~ 5.0034 5.003 1.03 1.9 2.0 01.1 2.1 2.2

CRC-AAA-2654-01 1H-NMR\DMSO CRC-270622/109 Reviewed By: Agglob 1002

Analysed By: 🕅

30 06 2022

