

CERTIFICATE OF ANALYSIS

1. Identification

Catalogue Number

Lot Number

10-GUY-11-3

Product Name

Atorvastatin Epoxydione Impurity

Synonyms

A791855

3-(4-Fluorobenzoyl)-2-(2-methyl-1-oxopropyl)-N,3-diphenyloxiranecarboxamide; USP Atorvastatin Related Impurity D; Atorvastatin EP Impurity D; Atorvastatin epoxydione

CAS Number

Solubility

Acetonitrile (Slightly), Chloroform 148146-51-4 (Slightly, Heated, Sonicated), DMSO (Slightly) Methanol (Slightly Sonicated

Source of Product Molecular Formula

C₂₆H₂₂FNO₄ Synthetic

Molecular Weight <u>Purity</u> 431.46 97%

2. Warnings

Not Determined

3. Analytical Information

Specifications Tests Appearance White to Off-White Solid **NMR** Conforms to Structure F NMR Conforms to Structure Conforms to Structure MS

Structure

Shipping Condition

This Product Is Stable To Be Shipped At Room

Temperature

Long Term Storage Conditions

4°C

Results

White Solid

Conforms

Conforms

Conforms

Additional Information

TLC Conditions: SiO₂; Hexanes: Ethyl Acetate = 7:3; Visualized with UV and AMCS; Rf = 0.65.

Purity is based on the analytical results of the tests performed. NMR and Elemental Analysis (if available) may have an accuracy of ± 2%. Isotopic purity is based on mass distribution observed.

The contents of the specifications are subject to change without advance notice, and the specification values displayed here are the most up to date values.

4. Signatures

Reviewed by C of A Approved by Reviewed by **Test Date Retest Date** Enie J. Beatons ubmy 3/5/2020 3/3/2027

Eric Beaton Toni Rantanen My Nguyen

Product Quality Specialist Manager, Quality Assurance **Quality Assurance Associate**