



Certificate of Analysis

Ledipasvir

Catalog Number: LE1002
Lot Number: 0726601
CAS Number: 1256388-51-8
Molecular Formula: C₄₉H₅₄F₂N₈O
Molecular Weight: 889.0
Storage: ≤ -20°C
Date of Manufacture: June 7, 2016
Retest Date: June 6, 2017

Test	Specification	Result
Appearance	White to off-white powder	Conforms
Purity (HPLC)	≥ 99.0%	99.85%
Assay	98.0 – 102.0%	99.73%
Identification	Retention time of major peak in the chromatogram corresponds to standard	Conforms
Residue on Ignition	≤ 0.1%	0.01%
Impurity (HPLC) Individual Total	≤ 0.15% ≤ 1.0%	0.05% 0.15%
Heavy Metals	≤ 10ppm	< 10ppm
Residual Solvents		
Acetone	≤ 5000ppm	Not detected
Toluene	≤ 890ppm	9ppm
Isopropyl Acetate	≤ 5000ppm	52ppm
Ethyl Acetate	≤ 5000ppm	269ppm
Methanol	≤ 3000ppm	725ppm
Acetonitrile	≤ 410ppm	Not detected
DMF	≤ 880ppm	Not detected
Dichloromethane	≤ 600ppm	Not detected
Ethanol	≤ 5000ppm	161ppm

Approved by:

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