

Gojira Fine Chemicals, LLC

Quality Products & Services Meeting Customer Needs
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Specification

Ledipasvir

 Catalog Number:
 LE1002

 Lot Number:
 0726601

 CAS Number:
 1256388-51-8

 Molecular Formula:
 C49H54F2N8O

Molecular Weight:889.0Storage:≤ -20°C

Retest Period: One year from the date of manufacture

Test	Specification
Appearance	White to off-white powder
Purity (HPLC)	≥ 99.0%
Assay	98.0 – 102.0%
Identification	Retention time of major peak in the chromatogram corresponds to standard
Residue on Ignition	≤ 0.1%
Impurity (HPLC) Individual Total	≤ 0.15% ≤ 1.0%
Heavy Metals	≤ 10ppm
Residual Solvents	
Acetone	≤ 5000ppm
Toluene	≤ 890ppm
Isopropyl Acetate	≤ 5000ppm
Ethyl Acetate	≤ 5000ppm
Methanol	≤ 3000ppm
Acetonitrile	≤ 410ppm
DMF	≤ 880ppm
Dichloromethane	≤ 600ppm
Ethanol	≤ 5000ppm

Approved:

Date: September 12, 2018

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Quality Manager

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