

CERTIFICATE OF ANALYSIS



Material: Fx-1006A micronized

Lot No: J-80162-191236

Code No: 79751

Lab No: QC-54328

Tested according to: DELMAR

<u>TEST</u>	<u>SPECIFICATIONS</u>	<u>RESULTS</u>
Description :	White to pink powder	White powder
Identification (IR) :	The sample spectrum conforms to that of the reference standard	Conform
Identification (¹ H NMR) :	The sample spectrum is similar to the RX829-PR-002 (Fx006A) REF STD Spectrum	Conform
	The spectrum contains the bands of Meglumine	Conform
Identification (HPLC)	Retention time of the major peak conforms to that of the reference standard.	Conform
Water content (KF) :	≤ 0.5 % w/w	0.3
Specific rotation :	-9.3° to -11.8°	-11.1
Residue on ignition :	≤ 0.1 % w/w	0.1
Heavy metals :	≤ 20 ppm	<20
Assay (HPLC) :	98.0 – 102.0% (w/w) dry basis	100.5
	98.0 – 102.0% (w/w) as is	100.3
Meglumine (IC)	37.0 -41.0 % (w/w)	38.5
Polymorphic form: (XRPD)	The sample diffractogram conforms to that of the reference standard.	Conform
Particle size (laser)	D(v, 0.5) ≤ 3.0 μm	2.0
	D(v, 0.9) ≤ 10.0 μm	4.6
Lithium content:	≤ 60 ppm	1
E-Coli	Not detected	Conform
Purity (HPLC) :	≥ 99.0 % w/w	99.9
	Bibenzoxazole Acid impurity	≤ 0.6 % w/w
	RX-829-01	≤ 0.10 % w/w
	RX-829-02	≤ 0.10 % w/w
	Diacyl impurity :	≤ 0.10 % w/w
	Unspecified impurities (each) :	≤ 0.10 % w/w

Date: August 28th 2019

Approved by: _____

Elise Isabel

Manager– Quality Control

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	AHBA ⁽¹⁾ :	≤ 0.05 %
	RX-829-00 ⁽¹⁾ :	≤ 0.05 %
	Diamide impurity ⁽¹⁾ :	≤ 0.05 %
	RX-01 Acid	≤ 0.10 % w/w
	Bibenzoxazole ester Impurity :	≤ 0.10% w/w
	Total impurities (specified and unspecified):	≤ 1.0 % w/w
Residual solvents (HS-GC) :	t-Butyl methyl ether :	9
	Acetone :	14
	Tetrahydrofuran :	Not Detected
	Methanol :	Not Detected
	Dichloromethane:	Not Detected
	Isopropyl Alcohol :	265
Residual solvents (HS-GC)	Pyridine:	Not Detected
	Toluene:	<7

⁽¹⁾ Results reported for these impurities are the ones obtained during the analysis of the intermediate RX-829-02 lot J-80141. The method D1568 is used for testing of purity of the intermediate RX-829-02. It is not applicable for RX-829-05. They are not accounted for in the Total impurities

Disposition : Meets specifications

Manufacturing date :

July 17th 2019

Re-test date: July 19th 2022

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Date: August 28th 2019

Approved by: Elise Isabel
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Manager– Quality Control

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