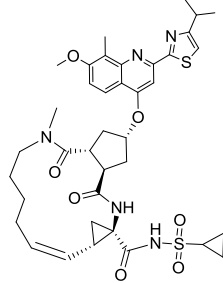


Certificate of Analysis

COA Number: COA-CB-201601001

Sample Code: CB-2001

Structure:



Product Name: (2R,3aR,11aS,12aR,14aR,Z)-N-(cyclopropylsulfonyl)-2-((2-(4-isopropylthiazol-2-yl)-7-methoxy-8-methylquinolin-4-yl)oxy)-5-methyl-4,14-dioxo-1,2,3,3a,4,5,6,7,8,9,11a,12,12a,13,14,14a-hexadecahydrocyclopenta[c]cyclopropa[g][1,6]diazacyclotetradecine-12a-carboxamide

Molecular Formula: C₃₈H₄₇N₅O₇S₂ Molecular Weight: 749.94

Batch No.: C150520-H-1512001 Batch Size: 7.5 kg

Manufacture Date: 2016.01.03 Test Date: 2016.01.05

Test	Method	Specification	Results	Reference
Appearance	Visual	White to off white powder	Off white powder	P15004-050
Solubility	Visual	Soluble in Acetone	Soluble	P15004-051
		Practically insoluble in Water	Insoluble	P15004-051
Identification	¹ H-NMR	Conform to structure	Confirmed	P15004-050
	IR	Similarly to the reference standard	Confirmed	P15004-052
	HPLC	The retention time should correspond to the standard solution	Confirmed	P15004-053~054
Water content	K.F.	≤ 0.5%	0.2%	P15004-058
Pb	ICP	≤ 20 ppm	< 5 ppm	P15004-052
Ru	ICP	≤ 20 ppm	< 5 ppm	P15004-052
Assay (on anhydrous)	HPLC (w/w)	98.0%~102.0%	99.4%	P15004-053~054

Purity	HPLC (a/a)	Purity≥99.0%	210nm: 100% 254nm: 99.8%	P15004-053~054
Impurity	HPLC (a/a)	Any individual impurity≤0.10%	254nm: RRT=0.815: 0.03% RRT=0.829: 0.04% RRT=0.835: 0.02% RRT=0.938: 0.03% RRT=1.080: 0.06%	P15004-053~054
		Total impurities≤1.0%	254nm: Total impurities: 0.2%	
Residue on Ignition	USP<281>	Report the result	0.08%	P15004-055
Residual Solvents	GC	MeOH ≤ 3000 ppm	N.D.	P15004-056~057
		EtOH ≤ 5000 ppm	11 ppm	
		DCM ≤ 600 ppm	N.D.	
		THF ≤ 720 ppm	18 ppm	
Specific Optical Rotation	0.5% Solution in Acetone at 25°C	Report the result	+33.6	P15004-052
Conclusion	The quality of product meets specifications.			

Prepared by/Data: _____

Reviewed by/Data: _____

Approved by/Data: _____

Revision History:

Version Number	Date of Change	Description of Changes
01	2016.01.14	New Established

If you are interested, please contact us

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