



Certificate of Analysis

Sirolimus (Rapamycin)

Product Name : Sirolimus (Rapamycin)
Mfg. Date : Jun 09, 2023
CAS No. : 53123-88-9

Lot No. : DL7593
Exp. Date : Jun 08, 2026
Batch Qty : 6.8kg

TESTS	SPECIFICATIONS		RESULTS
Appearance	White or almost white powder		White powder
Identification	HPLC		Conforms
Specific Rotation (CP)	-147° to -157°		-149°
Water (KF)	≤ 1.0%		0.18%
Residue on Ignition (CP)	≤ 0.5%		0.3%
Chloride (CP)	≤ 0.05%		< 0.05%
Related Substances (HPLC)	Seco-Sirolimus and 32-O-desmethyl sirolimus	≤ 1.0%	0.11%
	Prolylsirolimus	≤ 1.0%	Not detected
	12-ethyl sirolimus	≤ 1.0%	0.34%
	Isomer A	≤ 1.0%	0.08%
	Cis-stereoisomer of sirolimus (isomer c)	≤ 3.5%	3.5%
	Any individual impurity	≤ 0.4%	0.03%
	Total impurities (excluding isomer c)	≤ 3.0%	0.6%
Residual Solvents (GC)	Acetone	≤ 0.5%	< 0.5%
	Diethyl ether	≤ 0.5%	< 0.5%
	Methyl tert-butyl ether	≤ 0.5%	< 0.5%
	Dichloromethane	≤ 0.06%	< 0.06%
	Hexane	≤ 0.029%	< 0.029%
Assay (On Dried Basis) (HPLC) (CP2015)	98.0% - 102.0%		99.6%
Conclusion: The product meets the In-House specifications. Long Term Storage: Store in a sealed container at 2°C - 8°C in a fridge or freezer. ID Test was confirmed by FT-IR on-site. Distributed by Darmerica.			

Note: Analytical results transcribed from the original COA provided by Fuzhou Hongyisheng Pharmatech Co., Ltd. (China), Lot No. SRLM-20230609-01

Based on the review of above information, the lot stands released.

	Name	Title	Signature	Date
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Released by	Alianny Holguin	Quality Assistant	<i>Alianny Holguin</i>	08/28/2023