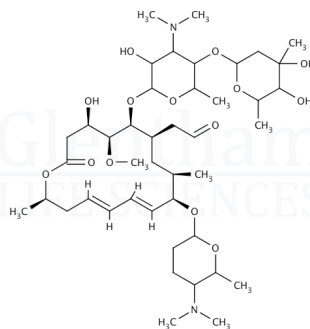


Certificate of Analysis

Product Name Spiramycin, EP grade
Glentham Code GA9612
CAS Number 8025-81-8
EINECS 232-429-6
MDL Number MFCD01314545
Batch Number 095RGN

Molecular Weight 843.05
Molecular Formula $C_{43}H_{74}N_2O_{14}$
Storage Temp. +4°C



Property	Specification	Batch 095RGN
Physical Description	White to pale yellow powder	Pale yellow powder
Identification	According to EP	Conforms
Solubility (10% in ethanol)	Clear, colourless to pale yellow solution	Clear, colourless solution
pH	8.5 - 10.5 (500mg in 5ml CH ₃ OH + 100ml H ₂ O)	9.5
Specific Optical Rotation	-80 - -85 °	-82 °
Any Individual Impurity	≤ 2.0%	1.3%
Total Impurities	≤ 10.0%	3.9%
Heavy Metals	≤ 20ppm	Conforms
Sulphated Ash	≤ 0.1%	Conforms
Composition	Spiramycin I: ≥ 80.0%	96.0%
	Spiramycin II: ≤ 5.0%	0.2%
	Spiramycin III: ≤ 10.0%	2.4%
	Total Spiramycins: ≥ 90.0%	98.6%
Loss on Drying	≤ 3.5%	0.8%
Assay	≥ 4100IU/mg (dried basis)	4434 IU/mg
Pharmacopoeia Specification(s)	EP	Conforms

Specification Version v1.0
Manufacture Date 2021-08-23
Re-Test Date 2029-09-27

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

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