Glentham LIFE SCIENCES

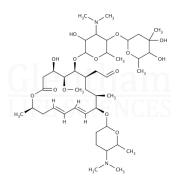
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Certificate of Analysis

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 ₂ O ₁₄
Storage Temp.	+4°C



Property	Specification	Batch 095RGN
Physical Description	White to pale yellow powder	Pale yellow powder
Identification	Accoridng to EP	Conforms
Solubility (10% in ethanol)	Clear, colourless to pale yellow solution	Clear, colourless solution
рН	8.5 - 10.5 (500mg in 5ml CH3OH + 100ml H2O)	9.5
Specific Optical Rotation	-8085 °	-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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