

Shandong Zesheng Chemical Co., Ltd.

Certificate of Analysis

Name	Framycetin Sulphate	MFG Date	Mar.16th,2020
Batch No.	FM- 20200316	Test Date	Mar.20th,2020
Batch Size	100.0 Kg	Expiration Date	Sep. 2023
Test	Specification		Result
Characters	A White or yellowish-white hygroscopic powder very soluble in water, very slightly soluble in alcohol, practically insoluble in acetone.		Yellowish-white powder Solubility; Complies
PH	6.0-7.0		6.3
Specific optical rotation	+52.5° - +55.5°		+53.9°
Identification	The retention time of a major peak meets the requirements.		Complies
	Impurity C meets the requirements B.		Complies
	Positive		Positive
Related substances	Impurity A: NMT 1.0 %		0.0%
	Impurity C: NMT 3.0%		1.0%
	Total of other impurities: NMT 3.0 %		0.02%
Sulphate(anhydrous)	27.0%-31.0%		28.8 %
Loss on drying	NMT 8.0%		4.7%
Sulphated ash	NMT 1.0%		0.4%
Potency	NLT 630 IU/mg (dried substance)		690 IU/mg (dried substance)
			658 IU/mg(as is)
Microbiological contamination (internal)	TAMC cfu/g	10 ³	15 cfu/g
	TYMC cfu/g	10 ²	7 cfu/g
	C.Coli /g	absent	absent

Conclusion: Complies with EP10.0

Analyst: Emily

Checker: Frank Fu

