



Certificate of analysis

Product name: Vincristine sulfate

Cas number: 2068-78-2

Molecular Formula: C₄₆H₅₆N₄O₁₀·H₂SO₄

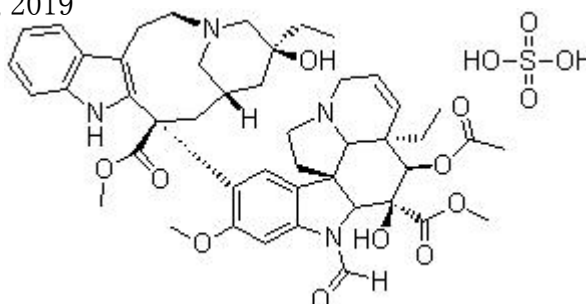
Molecular Weight: 923.04

Date of production: Oct. 21, 2019

Batch NO: 20191021

Exp Date: Oct. 20, 2021

Chemical structure:



Items		Specifications	Results
Appearance		White to slightly yellow, odorless, amorphous or crystalline powder	Conforms
Solubility		Freely Soluble in water or methanol, slightly soluble in ethanol.	Conforms
Identification	A. Infrared absorption	IR spectrum of the sample corresponds to that of the ref. standard.	Conforms
	B. Reaction of Sulfate	Positive for Sulfate	Positive
Appearance of solution		The solution (5mg/ml in water) is clear	Conforms
Related substances		Any other single impurity ≤ 1.0%	0.8%
		Total impurity ≤ 4.0%	1.5%
Residual organic solvents		Methanol ≤ 3000ppm Ethanol ≤ 5000ppm Methylene Chloride ≤ 600ppm Chloroform ≤ 60ppm Tetrahydrofuran ≤ 720ppm	47ppm 1291ppm 1ppm 13ppm 1ppm
Loss on drying		≤ 12.0%	8.5%
PH		3.5~4.5 (1.0mg/ml in water)	3.6
Bacterial Endotoxins		≤ 100 USP EU/mg	Conforms
Assay		95.0%~105.0 % (on the dried basis)	98.4%

Conclusion: It complies with the USP35 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F