

DATI ANALITICI

ANALYSIS REPORT

Date: March 2023

Product code 1200-139 Rev.13 of
May 2019

PENICILLIN G CLEMIZOLE + 0,5% LECITHIN + 0,3% POLYSORBATE 80 STERILE		Page 1 of 1
Declaration: EVULTIS SA		
Batch N°: AA-10-202211-02		Manufacturing date: Nov. 08, 2022
Quantity: 440,00 KGS		Expiry date: Nov 07, 2027
TESTS	SPECIFICATIONS	RESULTS
Appearance	A white or slightly yellow powder	Complies
Identification	Positive	Complies
Cristallinity	Birefringent	Complies
pH value	5.00 - 6.50	5.2
Water content	n.m.t. 0.5%	0.2%
Assay A.B. Penicillin G Clemizole equivalent Penicillin G (as such)	Not less than 810 I.U./mg	890 I.U./mg
Assay (on dry basis)	Not less than 814 I.U./mg	892 I.U./mg
Sterility	Sterile	Complies
Bacterial endotoxins	< 0.01 EU/100 IU	Complies
Injection test	Pass through needle 21G	Complies
Density (untapped)	≥ 0.35 g/ml	0.39 g/ml
Density (tapped)	≥ 0.50 g/ml	0.61 g/ml
Particle size	Approx 20% < 5µm	Complies
	Approx 99% < 100µm	Complies
	Approx 80% 5-50µm	Complies
Residual solvents	Ethyl Acetate ≤ 1500 ppm	26ppm
	Methanol ≤ 3000 ppm	99ppm

WE CERTIFY THIS PRODUCT COMES FROM A SYNTHETIC ORIGIN AND NOT FROM ANIMAL ORIGIN

The reported data are in agreement with manufacturer certificate of analysis

EVULTIS SA



Dr. Silvia Moiana

Technical Director