

CERTIFICATE OF ANALYSIS

Product: Qivitan LC 75 mg
Package size: 24 x 8 g
Batch-No.: 8510321
Man. Batch-No.: 8510321
Distributor/importer: Bistri-Vet
Country: Romania

Manufacturing date: 02.2021
Analysis date: 02.2021
Expiry date: 08.2022
Specification: P.851.S.04

Test	Method	Theoretical value	Specification limit	Result
Physical parameters				
Appearance	EP 2.2.1	-	white to light yellow, oily suspension	complies
Particle size ¹⁾	EP 2.9.37	-	90% < 10 µm 99% < 40 µm	complies
Deliverable mass [g]	EP 0945	8.0	7.2 – 8.8	8.0
Uniformity of mass	EP 2.9.40	-	must comply	complies
Viscosity [mPa.s]	P.851.AM02	-	130 – 230	151
Identity				
Cefquinome	P.851.AM01	-	must comply	complies
Assay				
Cefquinome (as sulfate) (mg/Injector)	P.851.AM01	75.0	71.3 – 78.8	75.6
Impurities				
5,6,7,8-Tetrahydroquinoline [%]	P.851.AM01	-	≤ 1.0	0.3
Cefotaxime acid [%]			≤ 1.0	n.d.
Unknown impurity [%]			≤ 0.5	0.4
Total impurities [%]			≤ 3.0	1.9
Microbiological purity				
Sterility ²⁾	EP 2.6.1	-	sterile	sterile

¹⁾ Particle size test performed by a contract lab.

n.d. = not detected LOQ = Limit of Quantitation

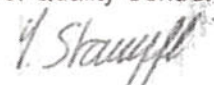
²⁾ Sterility test performed by a contract lab.

NA = Not Applicable

I hereby certify that the above information is authentic and accurate. This batch of product has been tested in full compliance with the GMP requirements. The product corresponds to the specifications in the Marketing Authorisation of the importing country.

Berne, 03. März 2021

Head of Quality Control



Y. Stampfli