

VIOSER S.A
QUALITY CONTROL DPT.

Control Tests on the Finished Product:

DEXTROSE 5% - ROMANIA - 250ML

Batch No: 704547
Prod. Date: 10/04/2017
Expiry Date: 10/04/2020

Test for	Nominal Value	According to	Method	Test Results
Appearance	Clear solution	Ph.Eur.,2.2.1	Visually	Conform
pH	3.5-5.5	Ph.Eur.,2.2.3	potentiometer	4.26
Glucose	50 g/l \pm 5%	Ph.Eur.,2.2.7	polarimeter	50.00
Discolouration (E 4cm/400nm)	< 0.050	Ph.Eur.,2.2.25	Spectrophotom.	0.004
5-HMF (E 1cm/284nm)	0.25	Ph.Eur., 2.2.25 0.4% test solution with reference to glucose	Spectrophotom.	0.033
Identification - Glucose	positive	Glucose-Oxidase- Reagent Paper		Conform
Sterility	sterile	Ph.Eur., 2.6.1	microbiolog.	Conform
Bacterial Endotoxins	< 0.25 IU/ml	Ph.Eur.,2.6.14	LAL-test	Conform
Expiry Date	shelf life: 3 years			04/2020
Extractable Volume	> declared volume	Ph.Eur.,2.9.17		Conform
Particulate Contamination -nonvisible particles-	$\geq 5 \mu\text{m} \leq 100/\text{ml}$ $\geq 10 \mu\text{m} \leq 25/\text{ml}$ $\geq 25 \mu\text{m} \leq 3/\text{ml}$	Ph.Eur.,2.9.19	Light Blockage	8.90 1.20 0.00

EXPERT RESPONSIBLES:

DATE: 13/06/2017

Chemist: 

Quality Control Manager

Biologist: 


Vasiliki Kefala