

VIOSER S.A
QUALITY CONTROL DPT.

Control Tests on the Finished Product:

DEXTROSE 10% ROMANIA - 500ml

Batch No: 701089
Prod. Date: 25/01/2017
Expiry Date: 25/01/2020

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	4.38
Glucose	100,0 g/L \pm 5%	Ph.Eur.,2.2.7	polarimeter	100.60
Discolouration (E 4cm/400nm)	< 0.050	Ph.Eur.,2.2.25	Spectrophotom.	0.003
5-HMF (E 1cm/284nm)	<0.25	Ph.Eur.,2.2.25 0.4% test solution with reference to glucose	Spectrophotom.	0.054
Identification - Glucose	Positive	Glucose-Oxidase- Reagent Paper		Conform
Sterility	sterile	Ph.Eur.,2.6.1	Microbiolog.	Conform
Bacterial Endotoxins	< 0.25 I.U/ml	Ph.Eur.,2.6.14	LAL-test	Conform
Expiry Date	shelf life: 3 years			01/2020
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	13.30 0.80 0.10

EXPERT RESPONSIBLES:

Chemist: 

Biologist: 

DATE: 15/03/2017

Quality Control Manager


Vasiliki Kefala