

VIOSER S.A
QUALITY CONTROL DPT.

Control Tests on the Finished Product:

DEXTROSE 10% ROMANIA - 250ml

Batch No: 611093
Prod. Date: 29/11/2016
Expiry Date: 29/11/2019

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	4.69
Glucose	100,0 g/L ± 5%	Ph.Eur.,2.2.7	polarimeter	99.70
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.	0.048
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			11/2019
Extractable Volume	> declared volume	Ph.Eur.,2.9.17		Conform
Particulate Contamination -nonvisible particles-	≥ 5 µm ≤ 100/ml ≥ 10 µm ≤ 25/ml ≥ 25 µm ≤ 3/ml	Ph.Eur.,2.9.19	Light Blockage	16.60 1.20 0.10

EXPERT RESPONSIBLES:

Chemist :

Biologist:

DATE: 15/12/2016

Quality Control Manager

Vasiliki Kefala