

Control Tests on the Finished Product:

DEXTROSE 5% - ROMANIA - 500ML

Batch No: 610852
Prod. Date: 17/10/2016
Expiry Date: 17/10/2019

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	4.58
Glucose	50 g/l ± 5%	Ph.Eur.,2.2.7	polarimeter	50.10
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.	0.037
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			10/2019
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	5.70 0.60 0.10

EXPERT RESPONSIBLES:

Chemist: 

Biologist: 

DATE: 10/11/2016

Quality Control Manager


Vasiliki Kefala