

Control Tests on the Finished Product:

DEXTROSE 5% - ROMANIA - 250ML

Batch No: 701033
Prod. Date: 16/01/2017
Expiry Date: 16/01/2020

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	4.54
Glucose	50 g/l ± 5%	Ph.Eur.,2.2.7	polarimeter	50.70
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.	0.034
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			01/2020
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	14.00 1.30 0.20

EXPERT RESPONSIBLES:

Chemist:

Biologist:

DATE: 01/02/2017

Quality Control Manager

Vasiliki Kefala