

VIOSER S.A
QUALITY CONTROL DPT.

Control Tests on the Finished Product:

DEXTROSE 5% - ROMANIA - 250ML

Batch No: 611089
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 | 4.62 |
| Glucose | 50 g/l ± 5% | Ph.Eur.,2.2.7 | polarimeter | 50.60 |
| 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. | 0.040 |
| 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 | | | 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 | 2.10 0.20 0.00 |

EXPERT RESPONSIBLES:

Chemist:

Biologist:

DATE: 14/12/2016

Quality Control Manager

Vasiliki Kefala