

Control Tests on the Finished Product:

DEXTROSE 10% ROMANIA - 250ml

Batch No: 702134
Prod. Date: 01/02/2017
Expiry Date: 01/02/2020

| 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 | 4.43 |
| Glucose | 100,0 g/L ± 5% | Ph.Eur.,2.2.7 | polarimeter | 100.50 |
| 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. | 0.033 |
| 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 | | | 02/2020 |
| 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 | 6.40 0.30 0.00 |

EXPERT RESPONSIBLES:

Chemist:

Biologist:

DATE: 20/02/2017

Quality Control Manager

Vasiliki Kefala