

CERTIFICATE OF ANALYSIS



Product: **Glucose-Lösung 40 % WDT ad. us. vet. (AM.,extern i. A.)**
Material no.: 90625
Batch number: 18N0196
Manufacturing date: 01.01.16
Expiration date: 01/2019
Container: 10 bottles of 500 ml

Wirtschaftsgenossenschaft
deutscher Tierärzte eG
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Parameter	Specification	Result
Analysis		
General		
imprint (batch number and date of expiry) is correct	complies	complies
Parameter		
Specification		
Result		
Analysis		
General		
text, layout and product insert (regulatory affairs)	complies	complies
certificate of analysis (ref. to test profil)	current COA corresponds with the reference COA	complies
primary packaging material	infusion bottle (soft plastic)	complies
appearance	clear, colourless, particle-free solution	complies
colour (COA)	colourless to NMT reference solution Y7	complies
extractable volume (COA)	>= 500.0 ml	530.0 ml
pH value (COA)	3.5 - 5.5	4.7
relative density (COA)	1.140 - 1.155 g/ml	1.154 g/ml
refractive index (COA)	1.387 - 1.393	1.390
Particle contamination, invisible particle > 10 µm (COA)	< 25 particle/ml	<1 particle/ml

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Particle contamination, invisible particle > 25 µm (COA)	< 3 particle/ml	<1 particle/ml
Identity		
glucose (COA)	complies	complies
Assay		
glucose (COA)	95 - 105 %	98 %
Purity		
5 - hydroxymethylfurfural and related subs (COA)	< 0.10	<0.10
Microbiology		
General		
sterility (COA)	complies	complies
bacterial endotoxins (COA)	< 0.25 IU/ml	<0.05 IU/ml

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The above mentioned batch complies with Marketing Authorization, German Drug Law, German Drug Manufacturing Regulation and EU GMP Guidelines.

Finished product

- complies with the specification
- is released for the market

The batch release in LIMS was executed on 8.2.16-09:44 by electronic signature of
Dr. Andreas Benen, Qualified Person, WDT eG, Plant Berenbostel.

LIMS is a computerised system. It is valid in accordance to EU GMP Guidelines, Annex 11. This certificate of analysis has been generated by LIMS.
The data in this document, as well as the documented decision of the batch release, are fully valid without manual signature.