

Werfft-Pharma KFT.
Szent Imre UT156/a
H 9028 Győr

Dr. The / ko 28.09.2015

Certificate of Analysis

Product : Belavit AD3E injekció A.U.V.
Product- No. : 1142114HUH
Batch : G2921-04
In : 100 ml
Quantity : 480 units
Order : 806771 / 2015
Production date : July 2015
Expiry date : July 2017
Date of analysis : 10.08.2015

Testing	Specification	Result
Characteristics		complies
Appearance	clear, yellow solution	complies
Clarity	clear	complies
Colour	not more intensely coloured than GY3	complies
Relative density	0.910 – 0.960	0.945
Refractive index	1.470 – 1.480	1.472
Viscosity	40.0 – 70.0 mPa*s	50.5 mPa*s
Visible particles*	max. 4.5 SE	
Identity		
Cholecalciferol	positive	positive
α- Tocopheryl acetate	positive	positive
Retinol Palmitate	positive	positive
Purity		
Impurities total	max. 3.0 %	1.5 %
Impurity single unknown (r.t.=0.3%) **	max. 1.0 %	1.0 %
Retinol	max. 1.0 %	0.1 %
Assay		
Cholecalciferol	2.38 – 2.63 mg/ml	2.41 mg/ml
α- Tocopheryl acetate	47.5 – 52.5 mg/ml	49.30 mg/ml
Retinol Palmitate	167.6 – 185.3 mg/ml	176.0 mg/ml
Microbiological quality		
Sterility	sterile	sterile
Filling quantity		
Extractable volume	min. 100 % of declaration	100 %

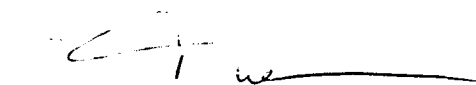
* Testing is performed during the in-process control!

** r.t. = reporting treshold


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I hereby certify that this batch has been manufactured, packed and tested under GMP conditions (in accordance with EC Guide to Good Manufacturing Practices for Medicinal Products). The documentation of the manufacturing and packaging process and testing is complete and has been reviewed and approved by the responsible personal. This batch is conform to its specification and is released for sale.



Dr. C. Themann
(Qualified person)



DR LENGYEL TAMÁS
KERESKEDELMI CÉLRA
FELSZABADITVA