



Certificate of Analysis

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Name of Product:	Werfalex Szuszpenzios Injekcio A.U.V [Alvetra Werfft Hungary]			
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
6231-02G	1,008	June 2016	June 2018	100 ml Clear Glass Vial
Active Ingredients:	• Cephalexin as Sodium (180 mg/ml)			
Storage Conditions:	Do not store above 25°C. Protect from light. Store out of reach of children.			

Analytical	Results	Specifications
Appearance	Conforms	An off white to cream, oily suspension.
Identification: • Cephalexin	Confirmed	• Identity confirmed.
Volume of Fill	102 % (102 ml)	100 to 108% of nominal fill.
Syringeability	Conforms	Passes easily through a 21G needle.
Resuspendability	Conforms	Resuspends ≤ 20 seconds.
Particle Size	Conforms	90% ≤ 55 µm.
	Conforms	50% ≤ 26 µm.
	Conforms	10% ≤ 10 µm.
Water Content	0.7 %	Not more than 2.0%.
Viscosity	106 cPs	50 to 500 cPs.
Degradation Products	0 %	Not more than 1% (individual).
	0 %	Not more than 2% (total).
Sterility	Conforms	Passes Ph. Eur test.
Assay: • Cephalexin	17.4 %w/v	• 17.1 to 18.9 %w/v.

I hereby certify that the above information is authentic and accurate in so far that the specification information is available to us and we confirm that our scientific findings are true. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site (Manufacturing Authorisation Number: ManA 2000) in full compliance with GMP requirements and in accordance with the specification provided to us. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Prepared By:

Date:

Goods Invoice Number:

Mate Hess
12-July-2016

APPROVED FOR THE HEAD OF QUALITY CONTROL

Stephen Mitchell
Qualified Person
& Quality Advisor

PASSED

Step A Mitchell

12 JUL 2016

DR Lengyel Tamás
KÉRESKEDELMI CÉLRA
FELSZABADÍTVA
DR LENGYEL TAMÁS
minőségügyi felelős



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Certificate of Manufacture

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Product Name: Werfalex Szuszpenzios Injekcio A.U.V
Product Code: 90665
Batch Number: 6231-02G
Fill Volume/Weight: 100 ml Clear Glass Vial

The above mentioned batch of product has been fabricated/manufactured, including packaging and quality control in full compliance with the Good Manufacturing Practice requirements of the Local Regulatory Authority. The batch processing, packaging and analysis records were reviewed and found to be in compliance with Good Manufacturing Practices.

Stephen Mitchell
Qualified Person
& Quality Advisor
PASSED

Stephen A Mitchell