

AURIZON FÜLCSEPP 10 ML  
Gysz:9C2619D  
Kisz:10ml  
SZÉKELY KFT részére

Lej:21/09/15  
Me.:Doboz

Medimpex Gy. Zrt.  
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**vetoquinol**  
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**CERTIFICATE OF ANALYSIS**

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FINISHED PRODUCT		
TESTS	SPECIFICATIONS	RESULTS
Product name :	AURIZON GTT FL 10ML HU RO	Analytical code : 442996
Pharmaceutical form :	Otic Solutions	Manufacturing date : 16/09/2019
Batch number :	9C2619D	Expiration date : 15/09/2021
Characteristics of solution	Homogeneous suspension	Pass
Color of suspension	Beige to yellow	Pass
Resuspendability	Pass	Pass
Extractable volume	$\geq 10.0 \leq 11.0$ ml	10.2 ml
Relative density	$\geq 0.960 \leq 0.980$	0.974
Particles size		
d50	$\leq 10 \mu\text{m}$	2 $\mu\text{m}$
d90	$\leq 25 \mu\text{m}$	4 $\mu\text{m}$
Marbofloxacin assay		
Marbofloxacin identity	Pass	Pass
Marbofloxacin content	$\geq 0.2850 \leq 0.3150$ %w/v	0.3029 % w/v
Marbofloxacin impurities		
Ro42-0253	$\leq 0.5$ %area	0.0 % area
Ro47-3012	$\leq 0.5$ %area	0.1 % area
Each unknown impurity	$\leq 0.1$ %area	<0.1 % area
Total unknown impurities	$\leq 0.5$ %area	<0.1 % area
Dexamethasone acetate assay		
Dexamethasone acetate identity	Pass	Pass
Dexamethasone acetate content	$\geq 0.0950 \leq 0.1050$ %w/v	0.1009 % w/v

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**LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE**

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VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

Meoszám:200300070MBT

6.pld. Kiadva: 20/06/03

**MEDIMPEX GYÓGYSZER ZRT.**  
1158 Bp., Rákospalotai határút 2.  
Nagyé Min. Biz. :  
Minőségbiztosító szakasszisztens  
Csak a piros színű hiteles

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FINISHED PRODUCT

Product name : AURIZON GTT FL 10ML HU RO

Analytical code : 442996

Pharmaceutical form : Otic Solutions

Manufacturing date : 16/09/2019

Batch number : 9C2619D

Expiration date : 15/09/2021

TESTS	SPECIFICATIONS	RESULTS
Dexamethasone acetate impurities		
Dexamethasone alcohol	$\leq 1.0$ %area	0.1 % area
Each unknown impurity	$\leq 1.0$ %area	0.1 % area
Total unknown impurities	$\leq 1.5$ %area	0.3 % area
Clotrimazole assay		
Clotrimazole identity	Pass	Pass
Clotrimazole content	$\geq 0.950$ $\leq 1.050$ %w/v	0.975 % w/v
Clotrimazole impurities		
2-chlorophenyldiphenylmethanol	$\leq 0.5$ %area	<0.2 % area
Propyl gallate assay		
Propyl gallate identity	Pass	Pass
Propyl gallate content	$\geq 0.0900$ $\leq 0.1100$ %w/v	0.0998 % w/v
Total aerobic microbial count (TAMC)	$\leq 100$ cfu/ml	<10 cfu/ml
Total yeasts and mould count (TYMC)	$\leq 10$ cfu/ml	<10 cfu/ml
Staphylococcus aureus	No growth	Pass
Pseudomonas aeruginosa	No growth	Pass

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in the current European Union rules for Good Manufacturing Practice for medicinal products for veterinary use, and that the finished product in all aspects answers the requirements laid down in the marketing authorisation.

Released by Qualified Person :

Adriana TASSI

Date :

12/12/2019 15:01:47

Decision :

FULL RELEASE

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