

AURIZON FÜLCSEPP 10 ML
 Gysz: 9C1496D Lej: 21/05/15
 Kisz: 10ml Me.: Doboz
 SZÉKELY KFT részére

MedimpeX Gy. Zrt.
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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML HU RO	Analytical code :	442996
Pharmaceutical form :	Otic Solutions	Manufacturing date :	16/05/2019
Batch number :	9C1496D	Expiration date :	15/05/2021

TESTS	SPECIFICATIONS	RESULTS
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	10.0 ml
Relative density	$\geq 0.960 \leq 0.980$	0.971
Particles size		
d50	$\leq 10 \mu\text{m}$	2 μm
d90	$\leq 25 \mu\text{m}$	4 μm
Marbofloxacin assay		
Marbofloxacin identity	Pass	Pass
Marbofloxacin content	$\geq 0.2850 \leq 0.3150$ %w/v	0.3032 % w/v
Marbofloxacin impurities		
Ro42-0253	≤ 0.5 %area	0.0 % area
Ro47-3012	≤ 0.5 %area	<0.1 % area
Each unknown impurity	≤ 0.1 %area	<0.1 % area
Total unknown impurities	≤ 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	0.1000 % w/v

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Meoszám: 191100004MBT

7.pld. Kiadva: 20/01/28

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 Nagyné Kári Éva
 Minőségbiztos Minőségirányítási Rendszer
 Csak a piros szín hiteles

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vetoquinol
ACHIEVE MORE TOGETHER
CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT

Product name : AURIZON GTT FL 10ML HU RO Analytical code : 442996
Pharmaceutical form : Otic Solutions Manufacturing date : 16/05/2019
Batch number : 9C1496D Expiration date : 15/05/2021

TESTS	SPECIFICATIONS	RESULTS
Dexamethasone acetate impurities		
Dexamethasone alcohol	≤ 1.0 %area	
Each unknown impurity	≤ 1.0 %area	0.1 % area
Total unknown impurities	≤ 1.5 %area	0.1 % area
Clotrimazole assay		0.2 % area
Clotrimazole identity	Pass	Pass
Clotrimazole content	$\geq 0.950 \leq 1.050$ %w/v	0.972 % w/v
Clotrimazole impurities		
2-chlorophenyldiphenylmethanol	≤ 0.5 %area	
Propyl gallate assay		< 0.2 % area
Propyl gallate identity	Pass	Pass
Propyl gallate content	$\geq 0.0900 \leq 0.1100$ %w/v	0.1004 % w/v
Total aerobic microbial count (TAMC)	≤ 100 cfu/ml	< 10 cfu/ml
Total yeasts and mould count (TYMC)	≤ 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 :

Date :

Decision :

Adriana TASSI

17/09/2019 12:38:14

FULL RELEASE

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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

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