

AURIZON FÜLCSEPP 10 ML
Gysz: 0C3246F
Kisz: 10ml
SZÉKELY KFT részére

Lej: 2022-10-19
Me: Doboz

Szállító:
Medimpex Gy. Zrt.
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FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML HU RO	Analytical code :	442996
Pharmaceutical form :	Otic Solutions	Manufacturing date :	19/10/2020
Batch number :	0C3246F	Expiration date :	19/10/2022

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	10.1 ml
Relative density	$\geq 0.960 \leq 0.980$	0.974
Particles size		
d50	$\leq 10 \mu\text{m}$	4 μm
d90	$\leq 25 \mu\text{m}$	6 μm
Marbofloxacin assay		
Marbofloxacin identity	Pass	Pass
Marbofloxacin content	$\geq 0.2850 \leq 0.3150$ %w/v	0.2969 % 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	0.1012 % w/v

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VETOSQUINOL S.A. Au Capital de 29.704.755 € SIRET 674 250 111 CRO171FC3 VESDULDRAY B 674 250 111

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FINISHED PRODUCT

Product name : AURIZON GTT FL 10ML HU RO **Analytical code :** 442996
Pharmaceutical form : Otic Solutions **Manufacturing date :** 19/10/2020
Batch number : 0C3246F **Expiration date :** 19/10/2022

TESTS	SPECIFICATIONS	RESULTS
Dexamethasone acetate impurities		
Dexamethasone alcohol	<= 1.0 %area	0.1 % area
Each unknown impurity	<= 1.0 %area	0.1 % area
Total unknown impurities	<= 1.5 %area	0.3 % area
Clotrimazole assay		
Clotrimazole identity	Pass	Pass
Clotrimazole content	>= 0.950 <= 1.050 %w/v	0.987 % w/v
Clotrimazole impurities		
2-chlorophenyldiphenylmethanol	<= 0.5 %area	<0.2 % area
Propyl gallate assay		
Propyl gallate identity	Pass	Pass
Propyl gallate content	>= 0.0900 <= 0.1100 %w/v	0.1012 % 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 : **Amelie LAVENS**
Date : 25/11/2020 14:21:46
Decision : FULL RELEASE

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