

AURIZON FÜLCSEPP 10 ML
Gysz: 1C1531E
Kisz: 10ml
SZÉKELY KFT részére

Lej: 2023-04-23
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 : 23/04/2021
Batch number : 1C1531E Expiration date : 23/04/2023

TESTS	SPECIFICATIONS	RESULTS
Characteristics of solution	Homogeneous suspension	Pass
Color of suspension	Beige to yellow	Pass
Resuspendability	Pass	Pass
Extractable volume	>= 10.0 <= 11.0 ml	10.0 ml
Relative density	>= 0.960 <= 0.980	0.975
Particles size		
d50	<= 10 µm	3 µm
d90	<= 25 µm	5 µm
Marbofloxacin assay		
Marbofloxacin identity	Pass	Pass
Marbofloxacin content	>= 0.2850 <= 0.3150 %w/v	0.3023 % 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	>= 0.0950 <= 0.1050 %w/v	0.1005 % w/v
Dexamethasone acetate impurities		
Total unknown impurities	<= 1.5 %area	0.3 % area
Dexamethasone alcohol	<= 1.0 %area	0.1 % area
Each unknown impurity	<= 1.0 %area	0.1 % area

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 : Amélie LAVENS

Date : 06 JUL 2021

Decision : ACCERTÉ

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

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TESTS	SPECIFICATIONS	RESULTS
Clotrimazole assay		
Clotrimazole identity	Pass	Pass
Clotrimazole content	>= 0.950 <= 1.050 %w/v	0.979 % 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	0.0998 % w/v
Staphylococcus aureus	No growth	Pass
Pseudomonas aeruginosa	No growth	Pass
Total Aerobic Microbial Count (TAMC)	<= 100 CFU/ml	
Total Yeasts and Moulds Count (TYMC)	<= 10 CFU/ml	

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Date : **06 JUL. 2021**
Decision : **ACCEPTÉ**

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

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