


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 :	13/03/2020
Batch number :	0C0856C	Expiration date :	13/03/2022

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	$\geq 0.960 \leq 0.980$	0.972
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	0.2969 % 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	0.1002 % w/v

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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

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VETODUINOL S.A. av Capital de 29.704.755 € SIRET 674 250 111 00017 (RCS VESUL GRAY B 674 250 111)

Meoszám:200600077MBT

10.pld. Kiadva: 20/10/14

MEDIMPEX GYÓGYSZER ZRT.
1158 Bp. Rákospalotai határút 2.
Nagyiné Kéri Éva
Minőségirányítási szakasszisztens
Csak a piros szín hiteles

AURIZON FÜLCSEPP 10 ML

Gysz:0C0856C

Kisz:10ml

SZÉKELY KFT részére

Lej:22/03/13

Me.:Doboz

Medimpex Gy. Zrt.

1158 Budapest

Rákospalotaihatárút2

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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 :	442986
Pharmaceutical form :	Otic Solutions	Manufacturing date :	13/03/2020
Batch number :	0C0856C	Expiration date :	13/03/2022
TESTS	SPECIFICATIONS	RESULTS	
Dexamethasone acetate impurities			
Dexamethasone alcohol	<= 1.0 %area	0.1 % area	
Each unknown impurity	<= 1.0 %area	0.2 % area	
Total unknown impurities	<= 1.5 %area	0.4 % area	
Clotrimazole assay			
Clotrimazole identity	Pass	Pass	
Clotrimazole content	>= 0.950 <= 1.050 %w/v	0.976 % w/v	
Clotrimazole impurities			
2-chlorophenyldiphenylmethanol	<= 0.5 %area	0.0 % area	
Propyl gallate assay			
Propyl gallate identity	Pass	Pass	
Propyl gallate content	>= 0.0900 <= 0.1100 %w/v	0.1001 % 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 :

Amelie LAVENS

19/05/2020 15:16:16

FULL RELEASE

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Meoszám:200600077MBT

10.pld. Kiadva: 20/10/14

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