

AURIZON FÜLCSEPP 10 ML
Gysz: 1C0957F
Kisz: 10ml
SZÉKELY KFT részére

Lej: 2023-03-11
Me: Doboz

Szállító:
Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút2
Tel: +36-1-414-6476
e-mail: qa@mpx.hu


vetoquinol
ACHIEVE MORE TOGETHER
CERTIFICATE OF ANALYSIS

Page 1/2

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML HU RO	Analytical code :	442996
Pharmaceutical form :	Otic Solutions	Manufacturing date :	11/03/2021
Batch number :	1C0957F	Expiration date :	11/03/2023

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	10.1 ml
Relative density	>= 0.960 <= 0.980	0.973
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	0.3040 % 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	0.1004 % w/v

This document has been produced electronically and is valid without a signature.

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

Magny-Vernois B.P.189 | 79204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETEOQUINOL S.A. au Capital de 29 764 756 € | SIRET 674 250 111 | 69017 | RCS VESUL GRAY B 674 253 111

AURIZON FÜLCSEPP 10 ML
Gysz: 1C0957F
Kisz: 10ml
SZÉKELY KFT részére

Lej: 2023-03-11
Me: Doboz

Szállító:
Medimpex Gy. Zrt.
1158 Budapest
Rákospalotaihatárút2
Tel: +36-1-414-6476
e-mail: qa@mpx.hu



Page 2/2

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML HU RO	Analytical code :	442996
Pharmaceutical form :	Otic Solutions	Manufacturing date :	11/03/2021
Batch number :	1C0957F	Expiration date :	11/03/2023

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	0.2 % area
Clotrimazole assay		
Clotrimazole identity	Pass	Pass
Clotrimazole content	>= 0.950 <= 1.050 %w/v	0.977 % 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	0.1003 % 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 :	01/06/2021 14:51:09
Decision :	FULL RELEASE

This document has been produced electronically and is valid without a signature.

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

Magny-Vernois - B.P.189 - 70204 Lure Cedex (France) - TEL : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETOCQUINOL S.A. au Capital de 29.704.755 € - SIRET n° 256 111 06019 - RCS VESOUL - BRAY B 674 253 111