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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CIMALGEX 80MG 32 RU	**Analytical code :**	439774
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	02/04/2019
Batch number :	9C1056B	**Expiration date :**	01/04/2022

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets		
Shape of tablets	Oblong tablets	Pass
Dimensions	21.5 x 8.5 mm	Pass
Color of tablets	White to beige, brown spotted	Pass
Breaking line	Presence of three breaking lines on both sides	Pass
Average mass and tablet mass variation		
Average mass	>=1045 <= 1155 mg	1112 mg
Tablet mass variation	Complies with Eur.Ph.2.9.40.	Pass
Quarter-tablet content uniformity	<= 15.0 (Eur. Ph.2.9.40)	5.2
Cimicoxib dissolution		
Average Dissolution	>= 75 % in 45 min	103 % Pass
Cimicoxib identity (HPLC)		
UV spectrum	Corresponds to reference	Pass
Retention time	Corresponds to reference	Pass
Cimicoxib assay (HPLC)		
Cimicoxib content	>= 76.0 <= 84.0 mg/tab	80.8 mg/tab.
Cimicoxib impurities (HPLC)		
Each unknown impurity	<= 0.3 % area	<0.1 % area
Total unknown impurities	<= 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 :	Brian LOYON
Date :	22/07/2019 16:17:48
Decision :	FULL RELEASE

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SPECIALITES VETERINAIRES
MAGNY-VERNOIS
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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CIMALGEX 8MG 32 RU	**Analytical code :**	439769
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	01/04/2019
Batch number :	9C1052C	**Expiration date :**	31/03/2022

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets		
Shape of tablets	Oblong tablets	Pass
Dimensions	10 x 4 mm	Pass
Color of tablets	White to beige, brown spotted	Pass
Breaking line	Presence on both sides	Pass
Average mass and tablet mass variation		
Average mass	>=104.5 <= 115.5 mg	111.0 mg
Tablet mass variation	Complies with Eur.Ph.2.9.40.	Pass
Half-tablet content uniformity	<= 15.0 (Eur.Ph.2.9.40)	9.1
Cimicoxib dissolution		
Average Dissolution	>= 75 % in 45 min	99.5 % Pass
Cimicoxib identity (HPLC)		
UV spectrum	Corresponds to reference	Pass
Retention time	Corresponds to reference	Pass
Cimicoxib assay (HPLC)		
Cimicoxib content	>= 7.60 <= 8.40 mg/tab	7.87 mg/tab.
Cimicoxib impurities (HPLC)		
Each unknown impurity	<= 0.3 % area	<0.1 % area
Total unknown impurities	<= 1.0 % area	0.1 % area

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Released by Qualified Person :	Paul-Adrien MATHON
Date :	15/07/2019 16:00:17
Decision :	FULL RELEASE

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CIMALGEX 30MG 32 RU	**Analytical code :**	439771
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	26/03/2019
Batch number :	9C0948C	**Expiration date :**	25/03/2022

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets		
Shape of tablets	Oblong tablets	Pass
Dimensions	15 x 6.5 mm	Pass
Color of tablets	White to beige, brown spotted	Pass
Breaking line	Presence on both sides	Pass
Average mass and tablet mass variation		
Average mass	>=392 <= 433 mg	417 mg
Tablet mass variation	Complies with Eur.Ph.2.9.40.	Pass
Half-tablet content uniformity	<= 15.0 (Ph. Eur. 2.9.40)	4.5
Cimicoxib dissolution		
Average Dissolution	>= 75 % in 45 min	101.167 % Pass
Cimicoxib identity (HPLC)		
UV spectrum	Corresponds to reference	Pass
Retention time	Corresponds to reference	Pass
Cimicoxib assay (HPLC)		
Cimicoxib content	>= 28.5 <= 31.5 mg/tab	29.7 mg/tab.
Cimicoxib impurities (HPLC)		
Each unknown impurity	<= 0.3 % area	0.1 % area
Total unknown impurities	<= 1.0 % area	0.1 % area

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Date :	16/07/2019 17:29:47
Decision :	FULL RELEASE

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CIMALGEX 80MG 32 RU	**Analytical code :**	439774
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	14/06/2018
Batch number :	8C1941C	**Expiration date :**	13/06/2021

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets		
Shape of tablets	Oblong tablets	Pass
Dimensions	21.5 x 8.5 mm	Pass
Color of tablets	White to beige, brown spotted	Pass
Breaking line	Presence of three breaking lines on both sides	Pass
Average mass and tablet mass variation		
Average mass	>=1045 <= 1155 mg	1123 mg
Tablet mass variation	Complies with Eur.Ph.2.9.40.	Pass
Quarter-tablet content uniformity	<= 15.0 (Eur. Ph.2.9.40)	5.8
Cimicoxib dissolution		
Average Dissolution	>= 75 % in 45 min	98.833 % Pass
Cimicoxib identity (HPLC)		
UV spectrum	Corresponds to reference	Pass
Retention time	Corresponds to reference	Pass
Cimicoxib assay (HPLC)		
Cimicoxib content	>= 78.0 <= 84.0 mg/tab	79.7 mg/tab.
Cimicoxib impurities (HPLC)		
Each unknown impurity	<= 0.3 % area	<0.1 % area
Total unknown impurities	<= 1.0 % area	<0.1 % area

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Released by Qualified Person :	Paul-Adrien MATHONNET
Date :	18/10/2018 18:44:49
Decision :	FULL RELEASE

Brian LOYON

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML RU	**Analytical code :**	0318879
Pharmaceutical form :	Otic Solutions	**Manufacturing date :**	25/03/2019
Batch number :	9C0946A	**Expiration date :**	24/03/2021

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	0.972
Particles size		
d50	<= 10 µm	2 µm
d90	<= 25 µm	4 µm
Marbofloxacin assay		
Marbofloxacin identity	Pass	Pass
Marbofloxacin content	>= 0.2850 <= 0.3150 %w/v	0.3006 % w/v
Marbofloxacine 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	0.1000 % w/v

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML RU	**Analytical code :**	0318879
Pharmaceutical form :	Otic Solutions	**Manufacturing date :**	25/03/2019
Batch number :	9C0946A	**Expiration date :**	24/03/2021

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	0.977 % 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	0.0998 % 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

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Released by Qualified Person :	Adriana TASSI
Date :	21/06/2019 11:34:54
Decision :	FULL RELEASE

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML RU	**Analytical code :**	0318879
Pharmaceutical form :	Otic Solutions	**Manufacturing date :**	29/03/2019
Batch number :	9C0999A	**Expiration date :**	28/03/2021

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	10.2 ml
Relative density	>= 0.960 <= 0.980	0.974
Particles size		
d50	<= 10 µm	2 µm
d90	<= 25 µm	3 µm
Marbofloxacin assay		
Marbofloxacin identity	Pass	Pass
Marbofloxacin content	>= 0.2850 <= 0.3150 %w/v	0.3015 % w/v
Marbofloxacine 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	0.0997 % w/v

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML RU	**Analytical code :**	0318879
Pharmaceutical form :	Otic Solutions	**Manufacturing date :**	29/03/2019
Batch number :	9C0999A	**Expiration date :**	28/03/2021

TESTS	SPECIFICATIONS	RESULTS
Dexamethasone acetate impurities		
Dexamethasone alcohol	<= 1.0 %area	0.2 % 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	0.971 % 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	0.0983 % 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 :	Adriana TASSI
Date :	29/07/2019 16:26:23
Decision :	FULL RELEASE

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