ORION

CERTIFICATE OF ANALYSIS

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1801780
Order Number: 80824835

Date of Manufacture: 17.08.2017
Date of Expiration: 08.2020
Storage: +15..25 °C
Specification: Hungary (108652) 20.03.2017

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
Colour of solution	100494-2	colourless	colourless	Espoo
Average volume in container	100229-2	nlt 10,0 ml	10,5 ml	Espoo
Volume in cont.	100229-2	10,0 ml - 11,0 ml	10,5 ml	Espoo
Partic.matter, presence of visib. partic	100473-2	practically no particles	practically no particles	Espoo
Clarity of solution	100493-2	clear	clear	Espoo
pH	100432-2	4,0 - 6,0	4,4	Espoo
Ident., atipamezole HCl, HPLC	100643-3	positive	positive	Espoo
Ident., methyl parahydroxybenzoate, HPLC	100643-3	positive	positive	Espoo
Assay, atipamezole HCl	100643-3	4,75 mg/ml - 5,25 mg/ml	5,05 mg/ml	Espoo
Assay, methyl parahydroxybenzoate	100643-3	0,90 mg/ml - 1,10 mg/ml	1,01 mg/ml	Espoo
Related substances	100643-3	nmt 1,0 %	<0,1 %	Espoo
Test for sterility	113205-1	sterile	sterile	Espoo
Bacterial endotoxins	100650-2	nmt 10 EU/ml	nmt 10 EU/ml	Espoo

Orion Corporation

Manufacturing license number 002871/06.08.00.04/2015

ORION PHARMA
Orionintie 1, 02200 ESPOO
P.O.Box 65, 02101 ESPOO
Tel. +358 10 4261
Fax +358 10 426 3815

Tengströminkatu 8, 20360 TURKU
P.O.Box 425, 20101 TURKU
Tel +358 10 42692
Fax +358 10 426 7777

Veljiikatu 8, 70700 KUOPIO
P.O.Box 1780, 70701 KUOPIO
Tel. +358 10 428 611
Fax +358 10 428 6444

Joensuunkatu 7, 24100 SALO
Tel +358 10 4261

Orion Corporation. Registered office and domicile: Orionintie 1, FI-02200 Espoo, Finland.

CERTIFICATE OF ANALYSIS

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1801780
Order Number: 80824835

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 02.11.2017 14:14:00 by a Qualified Person Katri Salonen

Orion Corporation

Manufacturing license number 002871/06.08.00.04/2015

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P.O.Box 1780, 70701 KUOPIO
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Fax +358 10 428 6444

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ORION

BATCH CERTIFICATE

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number:	133981
Batch Number:	1801780
Order Number:	80824835
Date of Manufacture:	17.08.2017
Date of Expiration:	08.2020
Quantity:	797 PCE
Marketing authorization number:	NP/V/0019/001 UP/I-322-05/13-01/856 V/NRP/02/1452, 3286/1/13, 1452 LT/2/02/1417/001, 140014 0022-1920-04.01.2013, 323-01-00026-14-001
Manufacturing site:	Orion Corporation, Espoo plant Orionintie 1 FI-02200 ESPOO
GMP Compliance of Manufact. site:	005703/06.08.02.00/2015
Quality control site:	Orion Corporation, Espoo plant Orionintie 1 FI-02200 ESPOO
GMP Compliance of Quality Ctrl site:	005703/06.08.02.00/2015
Packaging site:	Orion Corporation, Espoo plant Orionintie 1 FI-02200 ESPOO
GMP Compliance of Packaging site:	005703/06.08.02.00/2015

BATCH CERTIFICATE

ANTISEDAN 5MG/ML VET INJ 10ML HUEN

Product Number: 133981
Batch Number: 1801780
Order Number: 80824835

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 02.11.2017 14:14:00 by a Qualified Person Katri Salonen

Orion Corporation

Manufacturing license number 00287/06.08.00.04/2015

ORION PHARMA
Orionintie 1, 02200 ESPOO
P.O.Box 65, 02101 ESPOO
Tel. +358 10 4261
Fax +358 10 426 3815

Tengströminkatu 8, 20360 TURKU
P.O.Box 425, 20101 TURKU
Tel +358 10 42692
Fax +358 10 426 7777

Voltikatu 8, 70700 KUOPIO
P.O.Box 1780, 70701 KUOPIO
Tel. +358 10 428 611
Fax +358 10 428 6444

Joensuunkatu 7, 24100 SALO
Tel +358 10 4261

Orion Corporation. Registered office and domicile: Orionintie 1, FI-02200 Espoo, Finland.

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : AURIZON GTT FL 10ML HU RO
Analytical code : 442996
Pharmaceutical form : Otic Solutions
Manufacturing date : 09/01/2018
Batch number : 8C0090E
Expiration date : 09/01/2020

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	0.973
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	0.2938 % 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	0.1017 % w/v
Dexamethasone acetate impurities		
Total unknown impurities	<= 1.5 %area	0.1 % area
Dexamethasone alcohol	<= 1.0 %area	0.2 % 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 : Marie Bénédicte TESSIER
Date : 09 MARS 2018
Decision : ACCEPTÉ

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE
Magny-Vernois | B.P.189 | 70204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML HU RO	**Analytical code :**	442996
Pharmaceutical form :	Otic Solutions	**Manufacturing date :**	09/01/2018
Batch number :	8C0090E	**Expiration date :**	09/01/2020

TESTS	SPECIFICATIONS	RESULTS
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	0.0974 % 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 : Marie Bénédicte TESSIER

Date : 09 MARS 2018

Decision : ACCEPTÉ

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Magny-Vernois | B P.189 | 70204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56

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CERTYFIKAT SERII KOŃCOWEGO PRODUKTU LECZNICZEGO / BATCH CERTIFICATE FOR MEDICINAL PRODUCT

Name, strength/potency, dosage form	**Sedalin 35 mg/ml Oral Gel**
Package size	**10 ml**
Batch number of the finished product	**7E3155W**
Name of the destination country / countries of the batch	**Hungary**

Treść oświadczenia / Certification statement

Niniejszym certyfikuję, że wszystkie etapy wytwarzania końcowego produktu leczniczego zostały przeprowadzone w pełnej zgodności z wymaganiami Dobrej Praktyki Wytwarzania oraz wymaganiami pozwolenia (pozwoleń) i dokumentacji dotyczącej wprowadzania do obrotu produktu leczniczego docelowego kraju przeznaczenia, jeżeli produkt leczniczy jest przeznaczony na rynek Unii Europejskiej.

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and [when within the EU] with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Name of the Qualified Person certifying the batch	Mariola Kiszewska
Signature of Qualified Person certifying the batch	
Date of signature	2018 -04- 12

Vétoquinol Biowet Sp. z o.o.
Adres: ul. Kos. Gdyńskich 13-14, PL- 66-400 GORZOW WLKP.
tel. +48/95/ 728 55 00 ; 01, fax +48/95/ 735 90 43
Dział Logistyki Sprzedaży tel./fax +48/95/ 728 55 37
Łańcuch Dostaw tel./fax +48/95/ 728 55 50
e-mail: info.pl@vetoquinol.com www.vetoquinol.pl
Sąd Rejonowy w Zielonej Górze VIII Wydział Gospodarczy KRS o numerze 0000064225

Konto: Bank BGŻ BNP Paribas S.A.
EUR PL79 1600 1084 0004 0507 6260 2021 SWIFT: PPABPLPK
USD PL53 1600 1084 0004 0507 6260 2022 SWIFT: PPABPLPK
CHF PL25 1600 1084 0004 0507 6260 2023 SWIFT: PPABPLPK
PL37 1600 1084 0004 0507 6260 2001 PLN
REGON 210527414 NIP 599-01-08-560
Wysokość kapitału zakładowego 3.500.000 zł.

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : SEDALIN GEL 10ML HU
Batch number : 7E3155W
Manufacturing date : 13/11/2017
Expiration date : 12/11/2020

TESTS	SPECIFICATIONS	RESULTS
Appearance	Homogeneous,yellow-orange,transparent gel	Pass
Odour	Weak scent of acetic acid	Pass
Contents in unit container		
For container 10ml	>= 10.8 <= 11.6 g	11.2 g
pH	>= 5.0 <= 6.0	5.4
Relative density	>= 1.025 <= 1.045 g/ml	1.036 g/ml
Delivered volume	>= 10 ml	11 ml
Uniformity of mass of delivered doses	Complies	Pass
Viscosity (25°C, 7,5 per second)	>= 10000 <= 20000 mPa.s	12444 mPa.s
Identification		
Acepromazine	Confirm with RT	Pass
Methyl parahydroxybenzoate	Confirm with RT	Pass
Propyl parahydroxybenzoate	Confirm with RT	Pass
Assay		
Acepromazine	>= 95 <= 105 % declaration	101 % declaration
Acepromazine	>= 3.22 <= 3.56 % w/w	3.42 % w/w
Methyl parahydroxybenzoate	>= 95 <= 105 % declaration	100 % declaration
Methyl parahydroxybenzoate	>= 0.061 <= 0.067 % w/w	0.063 % w/w
Propyl parahydroxybenzoate	>= 95 <= 105 % declaration	105 % declaration
Propyl parahydroxybenzoate	>= 0.033 <= 0.037 % w/w	0.035 % w/w

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Vétoquinol Biowet Sp. z o.o.
Adres: ul. Kos. Gdyńskich 13-14,
Tel. +48/95/728 55 00 ÷1,
fax +48/95/728 55 00
PL- 66-400 GORZÓW WLKP
e-mail: info@vetoquinol.com
www.vetoquinol.pl
NIP 599-01-08-560
Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego 3.500.000 Zł

vetoquinol
ACHIEVE MORE TOGETHER

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : SEDALIN GEL 10ML HU
Batch number : 7E3155W
Manufacturing date : 13/11/2017
Expiration date : 12/11/2020

TESTS	SPECIFICATIONS	RESULTS
Purity (% ref to acepromazine)		
2-Acetylphenothiazine	<= 0.5 %	Not detected
Acepromazine-oxide	<= 1.0 %	0.1 %
Unknown individual	<= 0.5 %	<0.1 %
Unknown total	<= 1.0 %	<0.1 %
TAMC	<= 100 cfu/g	<1 cfu/g
TYMC	<= 10 cfu/g	<1 cfu/g
Escherichia coli in 1g	Absence	Pass

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in current European Union rules for Good Manufacturing Practice, for medicinal products for veterinary use, and the finish product in all aspects meets marketing authorization requirements.

Approved by QC : Przemyslaw KOWALSKI
Date : 04/04/2018 15:48:26

Released by Qualified Person : Mariola KISZEWSKA
Date : 12/04/2018 11:12:03
Decision : FULL RELEASE

Not tested - According to the requirements of the marketing authorization the parameter is not tested routinely.
Interpretation of the results of microbiological examination of non sterile products according to suitable Pharmacopoeia.
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Vétoquinol Biowet Sp. z o.o.
Adres: ul. Kos. Gdyńskich 13-14,
Tel. +48/95/728 55 00 +1,
fax +48/95/728 55 00
PL- 66-400 GORZÓW WLKP
e-mail: info@vetoquinol.com
www.vetoquinol.pl
NIP 599-01-08-560
Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego 3.500.000 Zł

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 50 10 CY HU RO	**Analytical code :**	426052
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	21/11/2017
Batch number :	7C3219X	**Expiration date :**	21/11/2019

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 9.8 <= 10.2 mm	10.1 mm
Average weight and uniformity of weight		
Average mass	>= 90.4 <= 100.0 mg	96.6 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5.	Pass
Resistance to crushing	>= 30 N	43 N
Disintegration test	<= 15 min	<3 min
Equilibrium relative humidity	<= 15 %	10 %
Amoxicillin dissolution rate	Q=85% within 30 min	99 %
Amoxicilin dissolution compliance	Complies with EP 2.9.3.	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	103 %
Clavulanic ac dissolution compliance	Complies with EP 2.9.3.	Pass
Amoxicillin and clavulanic acid identity (HPLC)		
Amoxicillin UV spectrum	Positive	Pass
Amoxicilin retention time	Positive	Pass
Clavulanic acid UV spectrum	Positive	Pass
Clavulanic acid retention time	Positive	Pass
Amoxicillin and clavulanic acid assay		
Amoxicillin content	>= 38.00 <= 42.00 mg/tablet	40.12 mg/tab.
Clavulanic acid content	>= 9.78 <= 10.82 mg/tablet	10.33 mg/tab.

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 50 10 CY HU RO	**Analytical code :**	426052
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	21/11/2017
Batch number :	7C3219X	**Expiration date :**	21/11/2019

TESTS	SPECIFICATIONS	RESULTS
Amoxicillin purity (HPLC)		
Imp.A	<= 1.0 %w/w	<0.3 % w/w
Imp.B	<= 1.0 %w/w	<0.3 % w/w
Imp.C	<= 1.0 %w/w	<0.3 % w/w
Imp.D	<= 1.0 %w/w	<0.3 % w/w
Imp.E	<= 1.0 %w/w	<0.3 % w/w
Imp.F	<= 1.0 %w/w	0.4 % w/w
Imp.G	<= 1.0 %w/w	0.5 % w/w
Imp.K	<= 1.0 %w/w	<0.3 % w/w
Any unidentified degradation product	<= 1.0 %w/w	<0.3 % w/w
Total unidentified degradation products	<= 2.0 %w/w	<0.3 % w/w
Total degradation products	<= 3.0 %w/w	0.9 % w/w
Clavulanic acid impurities (HPLC)		
Any unspecified degradation product	<= 1.0 %area	0.4 % area
Total degradation products	<= 2.0 %area	0.4 % 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 :	01/06/2018 12:42:20
Decision :	FULL RELEASE

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ACHIEVE MORE TOGETHER

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 50 10 CY HU RO	**Analytical code :**	426052
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	21/11/2017
Batch number :	7C3219H	**Expiration date :**	21/11/2019

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 9.8 <= 10.2 mm	10.1 mm
Average weight and uniformity of weight		
Average mass	>= 90.4 <= 100.0 mg	96.6 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5.	Pass
Resistance to crushing	>= 30 N	43 N
Disintegration test	<= 15 min	<3 min
Equilibrium relative humidity	<= 15 %	10 %
Amoxicillin dissolution rate	Q=85% within 30 min	99 %
Amoxicilin dissolution compliance	Complies with EP 2.9.3.	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	103 %
Clavulanic ac dissolution compliance	Complies with EP 2.9.3.	Pass
Amoxicillin and clavulanic acid identity (HPLC)		
Amoxicillin UV spectrum	Positive	Pass
Amoxicillin retention time	Positive	Pass
Clavulanic acid UV spectrum	Positive	Pass
Clavulanic acid retention time	Positive	Pass
Amoxicillin and clavulanic acid assay		
Amoxicillin content	>= 38.00 <= 42.00 mg/tablet	40.12 mg/tab.
Clavulanic acid content	>= 9.78 <= 10.82 mg/tablet	10.33 mg/tab.

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vetoquinol
ACHIEVE MORE TOGETHER

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 50 10 CY HU RO	**Analytical code :**	426052
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	21/11/2017
Batch number :	7C3219H	**Expiration date :**	21/11/2019

TESTS	SPECIFICATIONS	RESULTS
Amoxicillin purity (HPLC)		
Imp.A	<= 1.0 %w/w	<0.3 % w/w
Imp.B	<= 1.0 %w/w	<0.3 % w/w
Imp.C	<= 1.0 %w/w	<0.3 % w/w
Imp.D	<= 1.0 %w/w	<0.3 % w/w
Imp.E	<= 1.0 %w/w	<0.3 % w/w
Imp.F	<= 1.0 %w/w	0.4 % w/w
Imp.G	<= 1.0 %w/w	0.5 % w/w
Imp.K	<= 1.0 %w/w	<0.3 % w/w
Any unidentified degradation product	<= 1.0 %w/w	<0.3 % w/w
Total unidentified degradation products	<= 2.0 %w/w	<0.3 % w/w
Total degradation products	<= 3.0 %w/w	0.9 % w/w
Clavulanic acid impurities (HPLC)		
Any unspecified degradation product	<= 1.0 %area	0.4 % area
Total degradation products	<= 2.0 %area	0.4 % 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 :	09/03/2018 16:39:00
Decision :	FULL RELEASE

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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

Magny-Vernois | B.P.189 | 70204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
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ACHIEVE MORE TOGETHER

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 250 10 CY HU RO	**Analytical code :**	426055
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	11/01/2018
Batch number :	8C0131D	**Expiration date :**	10/01/2021

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 16.8 <= 17.2 mm	17.0 mm
Average weight and uniformity of weight		
Average mass	>= 452.2 <= 499.8 mg	478.5 mg
Uniformity of mass	Complies with EP 2.9.5.	Pass
Resistance to crushing	>= 60 N	99 N
Disintegration test	<= 15 min	<5 min
Equilibrium relative humidity	<= 15 %	9 %
Amoxicillin dissolution rate	Q=85% within 30 min	101 %
Amoxicilin dissolution compliance	Complies with EP 2.9.3.	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	99 %
Clavulanic ac dissolution compliance	Complies with EP 2.9.3.	Pass
Amoxicillin and clavulanic acid identity (HPLC)		
Amoxicillin UV spectrum	Positive	Pass
Amoxicilin retention time	Positive	Pass
Clavulanic acid UV spectrum	Positive	Pass
Clavulanic acid retention time	Positive	Pass
Amoxicillin and clavulanic acid assay		
Amoxicillin content	>= 190 <= 210 mg/tablet	207 mg/tab.
Clavulanic acid content	>= 48.9 <= 54.1 mg/tablet	51.5 mg/tab.

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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE
Magny-Vernois | B.P.189 | 70204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETOQUINOL S.A au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

vetoquinol
ACHIEVE MORE TOGETHER

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 250 10 CY HU RO	**Analytical code :**	426055
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	11/01/2018
Batch number :	8C0131D	**Expiration date :**	10/01/2021

TESTS	SPECIFICATIONS	RESULTS
Amoxicillin purity (HPLC)		
Imp.A	<= 1.0 %w/w	<0.3 % w/w
Imp.B	<= 1.0 %w/w	<0.3 % w/w
Imp.C	<= 1.0 %w/w	<0.3 % w/w
Imp.D	<= 1.0 %w/w	<0.3 % w/w
Imp.E	<= 1.0 %w/w	<0.3 % w/w
Imp.F	<= 1.0 %w/w	0.4 % w/w
Imp.G	<= 1.0 %w/w	0.5 % w/w
Imp.K	<= 1.0 %w/w	<0.3 % w/w
Any unidentified degradation product	<= 1.0 %w/w	<0.3 % w/w
Total unidentified degradation products	<= 2.0 %w/w	<0.3 % w/w
Total degradation products	<= 3.0 %w/w	0.9 % w/w
Clavulanic acid impurities (HPLC)		
Any unspecified degradation product	<= 1.0 %area	<0.3 % area
Total degradation products	<= 2.0 %area	<0.3 % area
Microbiological quality		
TAMC (once a year)	<= 1000 cfu/g	<100 cfu/g
TYMC (once a year)	<= 100 cfu/g	<100 cfu/g
Escherichia coli (once a year)	Absence in 1 g	Absence

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 :	16/03/2018 11:55:50
Decision :	FULL RELEASE

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Danilon A.U.U.

ESTEVE

LABORATORIOS Dr ESTEVE, S A
Pharmaceutical Plant

GMP Certificate number NCF/1609/001/CAT

CERTIFICATE OF MANUFACTURE AND BATCH RELEASE

Manufacturing site: **LABORATORIOS Dr. ESTEVE, S.A.**
San Marti, s/n - Poligono Industrial
08107 - Martorelles (Barcelona), SPAIN

Name of Product , Strength, Dosage form / Pack Size (type) :
Danilon Equidos (Suxibuzone) 1.5 g sachets
/ 60 x 10 g sac

Packaging Batch Number: 172769

Date of manufacture (according to EMEA/CVMP/453/01) 05-2017

Expiry Date: 05-2021

Results of analysis:
See attached Certificate of Analysis (CoA) number: 040000082150, 8900001 2567

Additional information:

- Destination (Country) Hungary

Certification:
I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured packaged and quality controlled at the above mentioned site in full compliance with the EU GMP requirements and with the specifications of the Marketing Authorisathion, including API origin and quality. The batch processing, packaging and analysis records were reviewed and found to be in compliance with the agreed specifications

(X) No significant deviations during manufacturing / packaging are reported.
( ) The following significant deviations were reported during manufacturing / packaging and properly investigated

Signature:

Gemma Boixda, Deputy Technical Director

Date:

(Qualified Person according Art. 49, Directive 2001 / 83 / EC)

END OF REPORT - Certificate of Manufacture & Batch Release

ESTEVE

LABORATORIOS Dr. ESTEVE S.A.
c/Sant Marti s/n
08107 Martorelles (Barcelona) SPAIN

CERTIFICATE OF ANALYSIS

Date of analysis: 18-12-2017

Product: DANILON EQUI DCP 60SOBX10G-H+RO+SLO
Batch: 172769
Date of manufacture: 16-05-2017

TEST	SPECIFICATIONS	RESULTS
Description	Yellow granules	Complies
Uniformity of mass		
Units	10 or 30	10
Mean		98.6 %
Standar Deviation		1.1
Acceptance Value	Complies Ph. Eur	2.5
CCF identification		
Suxibuzone	Positive	Positive
Saccharin sodium	Positive	Positive
Quinoline yellow (E-104) (UV)		
Identification	Positive	Periodic Test
Particule size		
> 0.21 mm	Less than 10 %	7 %
Dissolution rate Suxibuzone (UV)		
Units	6, 12 or 24	6
Mean	Q = 75 % in 45 min	92 %
Minimum		89 %
Complies acceptance criteria	Complies Ph. Eur./USP	Complies
Suxibuzone HPLC		
Identification	Positive	Positive
Assay	95.0 - 105.0 % (0.143 - 0.158 g/g)	99.1 %
Assay/sachet	95.0 - 105.0 % (1.425 - 1.575 g/sachet)	103.6 %
Degradation product		
Phenylbutane	Not more than 1.0 %	< 0.05 %
Microbiological purity	Complies Eur. Ph. 6.3 chapter 5.1.4	Complies

This is to certify that the product has been manufactured and tested according to current EC Good Manufacturing Practices (GMP) and other rules governing Medicinal Products in the EU at the above mentioned in accordance with the especifications in the Market ng Autorisation.

Signed and dated:

C. Colet
Qualified Person

19 DIC. 2017

AN: 040000082150.890000112567

CERTIFICATE OF ANALYSIS

KEFAVET VET 500 MG TABL 70 HUSIRO

Product Number: 144751
Batch Number: 1823537
Order Number: 80847203

Customers Batch Number: HH1380
Date of Manufacture: 04.08.2017
Date of Expiration: 07.2020
Storage: Below +30 °C
Specification: 10012784-02 (Mat:144751) 26.11.2015

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
Certificate of analysis	113389-1	conforms	conforms	
Certificate of conformity	113389-1	yes	yes	
Colour	113389-1	white to yellowish	white to yellowish	
Shape	113389-1	oblong, biconvex	oblong, biconvex	
Score	113389-1	on both sides	on both sides	
Code	113389-1	no	no	
Coating	113389-1	film-coated	film-coated	
Control of the finished product	113389-1	yes	yes	
Transport conditions	113389-1	conforms	conforms	

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 22.02.2018 16:22:52 by a Qualified Person Jouko Jukka

Orion Corporation
ORION PHARMA
Orionintie 1, 02200 ESPOO
P.O.Box 65, 02101 ESPOO
Tel. +358 10 4261
Fax +358 10 426 3515

Manufacturing licence number 005581 06.05.00 04.2017

Tengströminkatu 8, 20360 TURKU
P.O.Box 425, 20101 TURKU
Tel. +358 10 42692
Fax +358 10 426 2727

Valimotie 5, 70211 KUOPIO
P.O.Box 1780, 70101 KUOPIO
Tel. +358 10 428 611
Fax +358 10 428 6411

Joensuunkatu 7, 24101 SALO
Tel. +358 10 4261

Orion Corporation, Registered office and domicile: Orionintie 1, FI-02200 Espoo, Finland

BATCH CERTIFICATE

KEFAVET VET 500 MG TABL 70 HUSIRO

Product Number:	144751
Batch Number:	1823537
Order Number:	80847203
Customers Batch Number:	HH1380
Date of Manufacture:	04.08.2017
Date of Expiration:	07.2020
Quantity:	1353 PCE
Marketing authorization number:	2309/3/07 MGSZH ÁTI 110051 MR/V/0180/002
Manufacturing site:	Millmount Healthcare Limited Donore Road Industrial Estate DROGHEDA CO. MEATH 00000

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Electronically approved 22.02.2018 16:22:52 by a Qualified Person Jouko Jukka

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 50 10 CY HU RO	**Analytical code :**	426052
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	21/11/2017
Batch number :	7C3219X	**Expiration date :**	21/11/2019

TESTS	SPECIFICATIONS	RESULTS
Characteristics of tablets	Oblong, off-white to brownish sprinkled, scored	Pass
Length	>= 9.8 <= 10.2 mm	10.1 mm
Average weight and uniformity of weight		
Average mass	>= 90.4 <= 100.0 mg	96.6 mg
Uniformity of mass	Complies with Eur. Ph. 2.9.5.	Pass
Resistance to crushing	>= 30 N	43 N
Disintegration test	<= 15 min	<3 min
Equilibrium relative humidity	<= 15 %	10 %
Amoxicillin dissolution rate	Q=85% within 30 min	99 %
Amoxicilin dissolution compliance	Complies with EP 2.9.3.	Pass
Clavulanic ac dissolution rate	Q=80% within 30 min	103 %
Clavulanic ac dissolution compliance	Complies with EP 2.9.3.	Pass
Amoxicillin and clavulanic acid identity (HPLC)		
Amoxicillin UV spectrum	Positive	Pass
Amoxicilin retention time	Positive	Pass
Clavulanic acid UV spectrum	Positive	Pass
Clavulanic acid retention time	Positive	Pass
Amoxicillin and clavulanic acid assay		
Amoxicillin content	>= 38.00 <= 42.00 mg/tablet	40.12 mg/tab.
Clavulanic acid content	>= 9.78 <= 10.82 mg/tablet	10.33 mg/tab.

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	CLAVASEPTIN 50 10 CY HU RO	**Analytical code :**	426052
Pharmaceutical form :	Not Coated Tablets	**Manufacturing date :**	21/11/2017
Batch number :	7C3219X	**Expiration date :**	21/11/2019

TESTS	SPECIFICATIONS	RESULTS
Amoxicillin purity (HPLC)		
Imp.A	<= 1.0 %w/w	<0.3 % w/w
Imp.B	<= 1.0 %w/w	<0.3 % w/w
Imp.C	<= 1.0 %w/w	<0.3 % w/w
Imp.D	<= 1.0 %w/w	<0.3 % w/w
Imp.E	<= 1.0 %w/w	<0.3 % w/w
Imp.F	<= 1.0 %w/w	0.4 % w/w
Imp.G	<= 1.0 %w/w	0.5 % w/w
Imp.K	<= 1.0 %w/w	<0.3 % w/w
Any unidentified degradation product	<= 1.0 %w/w	<0.3 % w/w
Total unidentified degradation products	<= 2.0 %w/w	<0.3 % w/w
Total degradation products	<= 3.0 %w/w	0.9 % w/w
Clavulanic acid impurities (HPLC)		
Any unspecified degradation product	<= 1.0 %area	0.4 % area
Total degradation products	<= 2.0 %area	0.4 % 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 :	01/06/2018 12:42:20
Decision :	FULL RELEASE

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LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE

Magny-Vernois | B.P.189 | 70204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : ENROBIOFLOX 10% 50ML HU
Batch number : 8E0208D
Manufacturing date : 18/01/2018
Expiration date : 17/01/2021

TESTS	SPECIFICATIONS	RESULTS
Organoleptic characteristics	Clear,pale yellow solution.Color <= Y4	Pass
Content in unit container 50ml	>= 50 <= 55 ml	51 ml
Density	>= 1.035 <= 1.045 g/ml	1.042 g/ml
Product pH	>= 10.5 <= 12.0	11.8
Product identification		
Spectrophotometric method	Confirm with spectrum	Pass
HPLC method	RT confirmed	Pass
TLC method	Rf confirmed	Pass
Product purity		
Ciprofloxacin	<= 0.5 %	<0.2 %
Fluoroquinolone acid	<= 0.2 %	Not detected
Other impurities	<= 0.5 %	<0.2 %
Total impurities	<= 1 %	<0.2 %
Enrofloxacin assay	>= 9.5 <= 10.5 % m/v	10.0 % m/v
Benzyl alcohol assay	>= 1.49 <= 1.64 % m/v	1.55 % m/v
Product solubility		
Distilled water	Complies	Pass
Drinking water	Complies	Pass
TAMC	<= 100 cfu/ml	<10 cfu/ml
TYMC	<= 10 cfu/ml	<1 cfu/ml

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Vétoquinol Biowet Sp. z o.o.
Adres: ul. Kos. Gdyńskich 13-14,
Tel. +48/95/728 55 00 +1,
fax +48/95/728 55 00
PL- 66-400 GORZÓW WLKP
e-mail: info@vetoquinol.com
www.vetoquinol.pl
NIP 599-01-08-560
Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego 3.500.000 Zł

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT			
Product name :	ENROBIOFLOX 10% 50ML HU	**Manufacturing date :**	18/01/2018
Batch number :	8E0208D	**Expiration date :**	17/01/2021

TESTS	SPECIFICATIONS	RESULTS
Escherichia coli in 1ml	Absence	Pass

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in current European Union rules for Good Manufacturing Practice, for medicinal products for veterinary use, and the finish product in all aspects meets marketing authorization requirements.

Approved by QC :	Przemyslaw KOWALSKI	Released by Qualified Person :	Anita ABRAGIMOWICZ
Date :	08/02/2018 15:36:04	Date :	12/02/2018 10:00:01
		Decision :	FULL RELEASE

Not tested - According to the requirements of the marketing authorization the parameter is not tested routinely.
Interpretation of the results of microbiological examination of non sterile products according to suitable Pharmacopoeia.
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Adres: ul. Kos. Gdyńskich 13-14,
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Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego 3.500.000 Zł

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT	
Product name : ENROBIOFLOX 10% 50ML HU	**Manufacturing date :** 18/01/2018
Batch number : 8E0208D	**Expiration date :** 17/01/2021

TESTS	SPECIFICATIONS	RESULTS
Organoleptic characteristics	Clear,pale yellow solution.Color <= Y4	Pass
Content in unit container 50ml	>= 50 <= 55 ml	51 ml
Density	>= 1.035 <= 1.045 g/ml	1.042 g/ml
Product pH	>= 10.5 <= 12.0	11.8
Product identification		
Spectrophotometric method	Confirm with spectrum	Pass
HPLC method	RT confirmed	Pass
TLC method	Rf confirmed	Pass
Product purity		
Ciprofloxacin	<= 0.5 %	<0.2 %
Fluoroquinolone acid	<= 0.2 %	Not detected
Other impurities	<= 0.5 %	<0.2 %
Total impurities	<= 1 %	<0.2 %
Enrofloxacin assay	>= 9.5 <= 10.5 % m/v	10.0 % m/v
Benzyl alcohol assay	>= 1.49 <= 1.64 % m/v	1.55 % m/v
Product solubility		
Distilled water	Complies	Pass
Drinking water	Complies	Pass
TAMC	<= 100 cfu/ml	<10 cfu/ml
TYMC	<= 10 cfu/ml	<1 cfu/ml

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

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Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego 3.500.000 Zł

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT			
Product name :	ENROBIOFLOX 10% 50ML HU	**Manufacturing date :**	18/01/2018
Batch number :	8E0208D	**Expiration date :**	17/01/2021

TESTS	SPECIFICATIONS	RESULTS
Escherichia coli in 1ml	Absence	Pass

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in current European Union rules for Good Manufacturing Practice, for medicinal products for veterinary use, and the finish product in all aspects meets marketing authorization requirements.

Approved by QC :	Przemyslaw KOWALSKI	Released by Qualified Person :	Anita ABRAGIMOWICZ
Date :	06/02/2018 15:36:04	Date :	12/02/2018 10:00:01
		Decision :	FULL RELEASE

Not tested - According to the requirements of the marketing authorization the parameter is not tested routinely.
Interpretation of the results of microbiological examination of non sterile products according to suitable Pharmacopoeia.
This document has been produced electronically and is valid without a signature.

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Sąd Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 0000064225 Wysokość kapitału zakładowego 3.500.000 Zł

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PHARMACEUTICALS
MANUFACTURING LTD

Chanelle Pharmaceuticals Manufacturing Ltd.,
Dublin Road, Loughrea, Co. Galway, Ireland.
Tel: +353 (0)91 841788
Fax: +353 (0)91 842937
Web: www.chanellegroup.ie

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product:	**Rheumocam® 2.5mg**	**Man Date:**	**12 / 2017**
Customer:	**Orion**	**Expiry Date:**	**11 / 2022**
Livery:	**Hungary, Slovenia**	**Pack Size:**	**100's**
Batch No.:	**L33533/B**	**Quantity:**	**500**
Bulk Batch No.:	**L33533**		

TESTS	SPECIFICATIONS	RESULT
Appearance	Off white to pale yellow coloured, flat surface bevelled edged tablets with a breakline on one side.	Complies
Identification – HPLC	The retention time of the principal peak in the chromatogram of the assay preparation corresponds to that of the standard preparation as obtained in the assay.	Complies
Identification – UV	The absorption spectrum of the sample solution exhibits a maximum at about 340nm.	Complies
Disintegration Time	Not more than 15 minutes	3 minutes
Active Assay	Meloxicam 2.5 mg / tab ± 5% i.e. 2.375 mg/tab – 2.625 mg/tab	2.428mg/tab
Uniformity of Dosage Units	The requirements are met if the acceptance value of the first 10 dosage units is less than or equal to L1 (15.0). If the acceptance value is greater than L1, test the next 20 dosage units and calculate the acceptance value. The requirements are met if the final acceptance value of the 30 units is less than or equal to L1 (15.0) and no individual content of the dosage unit is less than (1-L2 x 0.01) M not more than (1 + L2.0.01) M in calculation of the acceptance value under mass variation. Unless otherwise specified, L1 is 15.0 and L2 is 25.0.	Complies (AV = 2.9)
Dissolution	NLT 75% dissolved after 45 minutes	88% Range: 86-90%
Microbiological Quality*	Conforms to Ph. Eur	Complies

* This is a non-routine test conducted on one in every 12 batches.

This product has been manufactured, analysed and packaged in accordance with the Marketing Authorisation EU/2/07/078/008 and with Directive 91/412/EEC

The product is fit for use and may be released for sale.

Checked By: Emma Kilmartin
Quality Assurance (Signature)
Date: 26/01/2018

Approved By: Anne Kelly
Qualified Person (Signature)
Date: 30/01/2018

Anne Kelly
Qualified Person (Print Name)

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MANUFACTURING LTD

Chanelle Pharmaceuticals Manufacturing Ltd.,
Dublin Road, Loughrea, Co. Galway, Ireland.
Tel: +353 (0)91 841786
Fax: +353 (0)91 842937
Web: www.chanellegroup.ie

Customer: Orion, Hungary / Poland

CERTIFICATE OF ANALYSIS

Product:	Quanifen
Man. Date:	03 / 2018
Exp. Date:	02 / 2021
Batch Number:	C34144/A

Test	Specification	Result
Description:	A round buff coloured tablet with quarter score.	Complies
Average Weight:	625mg ± 5% (Range: 594 mg - 656 mg)	622 mg
Weight Uniformity:	No more than 2 out of 20 of the individual weights must deviate from the average weight by more than 5% and none to deviate by more than 10.0%.	Complies
Identification A:	In HPLC analysis the retention time of Praziquantel & Fenbendazole in the sample chromatogram are comparable to the retention times in the standard chromatogram.	Complies
Identification B:	IR identification is positive	Complies
Assay:		
Fenbendazole:	500 mg (5% Limit) (475 mg – 525 mg / tablet)	480mg / tab
Praziquantel:	50 mg (5% Limit) (47.5 mg – 52.5 mg / tablet)	48.3mg / tab
Dissolution:	Fenbendazole: NLT 75% dissolved in 60 mins. Praziquantel: NLT 85% dissolved in 60 mins.	100% 99%
Friability:	< 1% after 3 minutes	0.3%
Hardness:	4 – 13 kp	8.5kp
Disintegration Time:	< 15 minutes	3.4 mins.
Moisture:	NMT 2%	1.4%
Microbial Purity*:	As per pH Eur	Complies

***Non-routine test every 6th Batch**

The above batch has been manufactured, packaged and tested in accordance with the Marketing Authorisation No. 1670/06 & 2879/11 MgSzH ATI and GMP.

The above batch is fit for use and may be released to the market.

Checked By: Emma Kilmurtry — Date: 08/06/2018
Quality Assurance *(Signature)*

Approved By: [signature] — Date: 11/06/2018
Qualified Person *(Signature)*

Sairaelle Reddy
Qualified Person *(Print Name)*

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MANUFACTURING LTD

Chanelle Pharmaceuticals Manufacturing Ltd.,
Dublin Road, Loughrea, Co. Galway, Ireland.
Tel: +353 (0)91 841788
Fax: +353 (0)91 842937
Web: www.chanellegroup.ie

Certificate of Compliance

Confirmation according to Annex 16 EU GMP Guide

Product:	Zantel Tablets
Dosage form and package size, if applicable:	50mg/500mg / 100's
Batch No.:	C34144/A
Date of Manufacturing:	30 /03 /2018
Expiry Date:	02 / 2021
Customer:	Orion, Hungry / Poland
Quantity :	998 x 100's

Manufacturing Instruction:
Document No.: 287

Testing Instruction:
Document No.: FPP162.1/10

Packaging Instruction:
Document No.: PWO1066/6

This is to certify that the information below for the batch mentioned above is authentic and accurate

The use of starting materials as well as manufacturing, packaging, in-process and final controls are:

- in accordance with GMP requirements and with the requirements of the local Regulatory Authorities,
- in agreement with the Marketing Authorisation records,
- in compliance with the above mentioned manufacturing instruction in accordance with the approved manufacturing procedure,
- in compliance with the above mentioned testing instruction in accordance with the approved testing procedure.

The manufacturing, packaging and testing documentation is complete and has been reviewed, and properly signed by the Head of Production and the Head of Quality Control. Deviations, if any, have been evaluated in line with the specified internal procedures and approved.

In the course of manufacturing, packaging and testing there have been

☒ No deviations which may influence the release of the product.
☐ Deviations which may influence the release of the product.
☐ Additional relevant information on the quality of the batch is attached.

Chanelle Pharmaceutical Manufacturing Ltd

Dublin Road, Loughrea, Co. Galway, Ireland

Emma Kilmartin — Date: 08/06/2018

Quality Assurance

P. McG — Date: 11/06/2018

Qualified Person

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : AURIZON GTT FL 10ML HU RO
Analytical code : 442996
Pharmaceutical form : Otic Solutions
Manufacturing date : 09/01/2018
Batch number : 8C0090E
Expiration date : 09/01/2020

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	0.973
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	0.2938 % 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	0.1017 % w/v
Dexamethasone acetate impurities		
Total unknown impurities	<= 1.5 %area	0.1 % area
Dexamethasone alcohol	<= 1.0 %area	0.2 % 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 : Marie Bénédicte TESSIER
Date : 09 MARS 2018
Decision : ACCEPTÉ

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE
Magny-Vernois | B.P.189 | 70204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

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CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name :	AURIZON GTT FL 10ML HU RO	**Analytical code :**	442996
Pharmaceutical form :	Otic Solutions	**Manufacturing date :**	09/01/2018
Batch number :	8C0090E	**Expiration date :**	09/01/2020

TESTS	SPECIFICATIONS	RESULTS
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	0.0974 % 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 : Marie Bénédicte TESSIER
Date : 09 MARS 2018
Decision : ACCEPTÉ

LABORATOIRE PHARMACEUTIQUE VÉTÉRINAIRE
Magny-Vernois | B.P.189 | 70204 Lure Cedex (France) | TÉL. : +33 (0) 3 84 62 55 55 - FAX : +33 (0) 3 84 62 55 56
VETOQUINOL S.A. au Capital de 29.704.755 € | SIRET 676 250 111 00017 | RCS VESOUL GRAY B 676 250 111

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product name : SEDALIN GEL 10ML HU **Manufacturing date :** 13/11/2017

Batch number : 7E3155H **Expiration date :** 12.11.2020

TESTS	SPECIFICATIONS	RESULTS
Appearance	Homogeneous,yellow-orange,transparent gel	Pass
Odour	Weak scent of acetic acid	Pass
Contents in unit container		
For container 10ml	>= 10.8 <= 11.6 g	11.2 g
pH	>= 5.0 <= 6.0	5.4
Relative density	>= 1.025 <= 1.045 g/ml	1.036 g/ml
Delivered volume	>= 10 ml	11 ml
Uniformity of mass of delivered doses	Complies	Pass
Viscosity (25°C, 7.5 per second)	>= 10000 <= 20000 mPa.s	12444 mPa.s
Identification		
Acepromazine	Confirm with RT	Pass
Methyl parahydroxybenzoate	Confirm with RT	Pass
Propyl parahydroxybenzoate	Confirm with RT	Pass
Assay		
Acepromazine	>= 95 <= 105 % declaration	101 % declaration
Acepromazine	>= 3.22 <= 3.56 % w/w	3.42 % w/w
Methyl parahydroxybenzoate	>= 95 <= 105 % declaration	100 % declaration
Methyl parahydroxybenzoate	>= 0.061 <= 0.067 % w/w	0.063 % w/w
Propyl parahydroxybenzoate	>= 95 <= 105 % declaration	105 % declaration
Propyl parahydroxybenzoate	>= 0.033 <= 0.037 % w/w	0.035 % w/w

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Vétoquinol Biowet Sp. z o.o.
Zielona Góra, Poland, PL 65-127,
Tel. +48/68 728 65 00
Fax +48/68 728 65 60
e-mail: info@vetoquinol.com
www.vetoquinol.pl
NIP 599-01-08 560
Sąd Rejonowy w Zielonej Górze V Wydział Gospodarczy KRS o numerze 0000164225 Wysokość kapitału zakładowego 3.030.000 zł

vetoquinol
ACHIEVE MORE TOGETHER

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TESTS	SPECIFICATIONS	RESULTS
Purity (% ref to acepromazine)		
2-Acetylphenothiazine	<= 0.5 %	Not detected
Acepromazine-oxide	<= 1.0 %	0.1 %
Unknown individual	<= 0.5 %	<0.1 %
Unknown total	<= 1.0 %	<0.1 %
TAMC	<= 100 cfu/g	<1 cfu/g
TYMC	<= 10 cfu/g	<1 cfu/g
Escherichia coli in 1g	Absence	Pass

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in current European Union rules for Good Manufacturing Practice, for medicinal products for veterinary use, and the finish product in all aspects meets marketing authorization requirements.

Approved by QC : Przemyslaw KOWALSKI
Date : 19/12/2017 15:56:24

Released by Qualified Person : Anita ABRAGIMOWICZ
Date : 19/01/2018 11:43:50
Decision : FULL RELEASE

Not tested - According to the requirements of the marketing authorization the parameter is not tested routinely.
Interpretation of the results of microbiological examination of non sterile products according to suitable Pharmacopoeia.
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Vétoquinol Biowet Sp. z o.o.
Adres: ul. Kpt. Gdyńskich 13-14,
Tel.: (48/95/728 55 00 +1,
Fax (48/95/728 55 00
PL- 66-200 ŚWIEBODZIN WLKP
e-mail: infoldvetoquinol.com
www.vetoquinol.pl
NIP 599 01 08 560
Sąd Rejonowy w Zielonej Górze VIII Wydział Gospodarczy KRS o numerze 0000066229. Wysokość kapitału zakładowego 3 130 000 Zł