chanelle
PHARMACEUTICALS
MANUFACTURING LTD

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CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Zeronil 67mg Solutie Spot-On pentru câini de talie mica 6's
Customer: Montero
Livery: Romania
Bulk Batch No.: 19030

Man Date: 08/2019
Expiry Date: 07/2021
Quantity: 1455 x 6's
Packing Batch No.: 19030E/2

TESTS	SPECIFICATIONS	RESULT
Appearance	Clear, pale amber solution with faint characteristic odour.	Complies
Colour	This product is not more intense than the permanent colour glass standard Y7	Complies
Identification: Fipronil UV by HPLC	The chromatography of the HPLC/UHPLC assay exhibits major peaks due to Fipronil the retention time of which is comparable to those exhibited in the chromatogram of the standard.	Complies
2nd Identification: Fipronil UV by PDA	The UV spectrum of the fipronil peak in the sample is in accordance with the UV spectra of the fipronil peak in the standard.	Complies
Identification: Butylhydroxyanisole	The chromatography of the HPLC assay exhibits major peaks due to butylhydroxyanisole the retention time of which is comparable to those exhibited in the chromatogram of the standard.	Complies
Identification: Butylhydroxytoluene	The chromatography of the HPLC assay exhibits major peaks due to butylhydroxytoluene the retention time of which is comparable to those exhibited in the chromatogram of the standard.	Complies
Assay: Fipronil	95 – 105% of the label claim 67mg ± 5% (Limits 63.65 – 70.35mg)	66.355mg
Assay: Butylhydroxyanisole	90 – 110% of the label claim 0.134mg/pipette ± 10% (Limits 0.121 – 0.147mg)	0.131mg
Assay: Butylhydroxytoluene	90 – 110% of the label claim 0.067mg/pipette ± 10% (Limits 0.0603 – 0.0737mg)	0.066mg
Impurity A:	≤ 1.0%	0.079%
Impurity B:	≤ 1.0%	0.251%
Single unknown impurity::	≤ 1.0%	< LOQ
Total impurities:	≤ 3.0%	0.330%
Moisture	Not more than 1.5%	0.24%
Uniformity of Dosage Units: (Acceptance Value)	Conforms to Ph. Eur. 2.9.40 Acceptance Value ≤ 15.0	0.48
Microbial Purity*	Conform to Ph. Eur. 5.1.4 NMT 10^2 bacteria, NMT 10^1 fungi per gram Absence of *S. aureus* & *P. aeruginosa*	Non-Routine Test.

* This is a non-routine test conducted on one in every 10 batches manufactured.

Results have been transcribed from Realoch Pharma Certificate of Analysis/Conformance.

This product has been manufactured, analysed and packaged in accordance with the relevant Marketing Authorisation No. 170238. There was one deviation associated with the above batch, reference RDEV-19-065, which has been assessed and there is no adverse impact on product quality, safety or efficacy. The product is fit for use and may be released for sale to Market.

Checked By: _____ Date: 22/10/2019
Quality Assurance (Signature)

Approved By: _____ Date: 22/10/2019
Qualified Person (Signature)

_____
Qualified Person (Print Name)