PN0110/13-2

chanelle
PHARMACEUTICALS
MANUFACTURING LTD

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CERTIFICATE OF ANALYSIS / CONFORMANCE

Product:	Controline 67mg		
Customer:	Pfizer Animal Health	Man Date:	01 / 2013
Livery:	Hungary, Poland	Expiry Date:	12 / 2014
Batch No.:	28101/3A12		

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	The chromatography of the HPLC assay exhibits a major peak due to Fipronil the retention time of which is comparable to those exhibited in the chromatogram of the standard	Complies
2nd Identification: Butylhydroxyanisole	The UV spectra 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 a major peak 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 a major peak 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)	67.392mg
Assay: Butylhydroxyanisole	90 – 110% of the label claim 0.134mg ± 10% (Limits 0.121 – 0.147mg)	0.136mg
Assay: Butylhydroxytoluene	90 – 110% of the label claim 0.067mg ± 10% (Limits 0.060 – 0.074mg)	0.067mg
Impurity A: (5-amino-1-(2,6-dichloro-4-)trifluoromethyl)phenyl)-4-(trifluoromethythio)1H-pyrazole-3-carbonitrile	≤ 1.0%	0.0209%
Impurity B: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(trifluoromethylsulfonyl)-1H-pyrazole-3-carbonitrile	≤ 1.0%	0.0405%
Single unknown impurity::	≤ 1.0%	0.0100%
Total impurities::	≤ 4.0%	0.0771%
Moisture	Not more than 2.0%	0.14%
Uniformity of Dosage Units: (Acceptance Value)	Conforms to Ph. Eur. 2.9.40 Acceptance Value ≤ 15.0	2.6%
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*	Complies

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

This product has been manufactured, analysed and packaged in accordance with the relevant Marketing Authorisation no. 3114/3/12, 2202/12

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

Checked By: _____ Date: 25/04/13
Quality Assurance (Signature)

Approved By: _____ Date: 25/04/13
Qualified Person (Signature)

_____
Qualified Person (Print Name)