PLO 113/13

chanelle
PHARMACEUTICALS
MANUFACTURING LTD

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CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Controline 402mg
Customer: Pfizer Animal Health
Livery: Hungary, Poland
Batch No.: 28105/3A20

Man Date: 01 / 2013
Expiry Date: 12 / 2014

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 402mg ± 5% (Limits 381.9 – 422.1mg)	390.000mg
Assay: Butylhydroxyanisole	90 – 110% of the label claim 0.804mg ± 10% (Limits 0.724 – 0.884mg)	0.797mg
Assay: Butylhydroxytoluene	90 – 110% of the label claim 0.402mg ± 10% (Limits 0.362 – 0.442mg)	0.389mg
Impurity A: (5-amino-1-(2,6-dichloro-4-)trifluoromethyl)phenyl)-4-(trifluoromethythio)1H-pyrazole-3-carbonitrile	≤ 1.0%	0.0211%
Impurity B: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(trifluoromethylsulfonyl)-1H-pyrazole-3-carbonitrile	≤ 1.0%	0.0393%
Single unknown impurity::	≤ 1.0%	0.0101%
Total impurities:	≤ 4.0%	0.076%
Moisture	Not more than 2.0%	0.09%
Uniformity of Dosage Units: (Acceptance Value)	Conforms to Ph. Eur. 2.9.40 Acceptance Value ≤ 15.0	1.0
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.

This product has been manufactured, analysed and packaged in accordance with the relevant Marketing Authorisation no. 3117/3/12, 2205/12.
The product is fit for use and may be released for sale.

Checked By: _____ Date: 15/02/13
Quality Assurance (Signature)

Approved By: _____ Date: 15/02/13
Qualified Person (Signature)

DAREN DALY
Qualified Person (Print Name)

PN043/13/4

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CERTIFICATE OF CONFORMITY

Product:	**Controline 402mg**
Country:	**Hungary, Poland**
Bulk Batch Number:	**28105**
Packing Batch Number:	**3A20**
Exp. Date:	**12 / 2014**
Pack Size:	**3's**
Quantity:	**578 x 10**

I, the undersigned, have examined the Certificate of Analysis from Bob Martin of the above product and can confirm that this batch has been packed in accordance with the Marketing Authorisation no 3117/3/12, 2205/12 and to GMP.

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

Approved By: Darren Daly Date: 15/02/13.
Qualified Person (Signature)

DARREN DALY.
Qualified Person (Print Name)