

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Controline 67mg
Customer: Pfizer Animal Health
Livery: Hungary, Poland
Batch No.: 28101/3A12

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
2 nd 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	67.392mg
Assay: Butylhydroxyanisole	67mg ± 5% (Limits 63.65 – 70.35mg)	0.136mg
Assay: Butylhydroxytoluene	90 – 110% of the label claim 0.134mg ± 10% (Limits 0.121 – 0.147mg)	0.067mg
Impurity A: (5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(trifluoromethylthio)1H-pyrazole-3-carbonitrile	90 – 110% of the label claim 0.067mg ± 10% (Limits 0.060 – 0.074mg)	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%	
Total impurities:	≤ 4.0%	0.0100%
Moisture	Not more than 2.0%	0.0771%
Uniformity of Dosage Units: (Acceptance Value)	Conforms to Ph. Eur. 2.9.40 Acceptance Value ≤ 15.0	0.14%
Microbial Purity*	Conform to Ph. Eur. 5.1.4 NMT 10 ² bacteria, NMT 10 ¹ fungi per gram Absence of <i>S. aureus</i> & <i>P. aeruginosa</i>	2.6%
		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: [Signature] Date: 25/02/13
Quality Assurance (Signature)

Approved By: [Signature] Date: 25/02/13
Qualified Person (Signature)

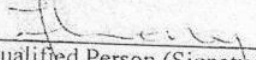
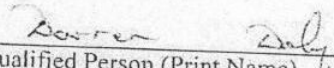
AGREEN DALY
Qualified Person (Print Name)

CERTIFICATE OF CONFORMITY

Product: Controline 67mg
Country: Hungary, Poland
Bulk Batch Number: 28101
Packing Batch Number: 3A12
Exp. Date: 12 / 2014
Pack Size: 3's
Quantity: 764 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 3114/3/12, 2202/12 and to GMP.

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

Approved By:  Date: 25/02/13
Qualified Person (Signature)

Qualified Person (Print Name)