

PN0111/13

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Controline 268mg
Customer: Pfizer Animal Health
Country: Hungary, Poland
Batch No.: 281043A13

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

TESTS	SPECIFICATIONS	RESULT
Appearance	Clear, pale amber solution with faint characteristic odour. This product is not more intense than the permanent colour glass standard Y7	Complies
Colour		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 268mg ± 5% (limits 254.6 – 281.4mg)	265.231mg
Assay: Butylhydroxyanisole	90 – 110% of the label claim 0.536mg ± 10% (limits 482.6 – 0.590mg)	0.530mg
Assay: Butylhydroxytoluene	90 – 110% of the label claim 0.268mg ± 10% (limits 0.241 – 0.295mg)	0.253mg
Impurity A:	≤ 1.0%	0.0201%
(5-aminio-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(trifluoromethylthio)-1H-pyrazole-3-carbonitrile		
Impurity B:	≤ 1.0%	0.0374%
5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(trifluoromethylsulfonyl)-1H-pyrazole-3-carbonitrile		
Single unknown impurity:	≤ 1.0%	
Total impurities:	≤ 4.0%	0.0004%
Moisture	Not more than 2.0%	0.0722%
Uniformity of Dosage Units: (Acceptance Value)	Conforms to Ph. Eur. 2.9.40 Acceptance Value ≤ 15.0	0.09%
Microbial Purity*	Conform to Ph. Eur. 5.1.4 NMT 10 ⁶ bacteria, NMT 10 ⁵ fungi per gram Absence of <i>S. aureus</i> & <i>P. aeruginosa</i>	1.7

* 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. 3116/3/12, 2204/12.

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

Checked By: [Signature] Date: 15/09/13
Quality Assurance (Signature)
Approved By: [Signature] Date: 15/09/13
Qualified Person (Signature)
Qualified Person (Print Name): DAVID DACEY

Director: Michael H Burke, Chanelle McCoy, Michael J Burke, Hilary Burke

Registration No. 101015

Diszpo: PN-ZA13000387 Vevó: Alpha-Vet 8000 File név: PN00007382 Egyedi sorszám: PN0000067758 2 másolat
Szállító: Zoetis Hungary Kft. Oldal/lap 2 / 1 Anyaglap: PN0111/13
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2013.04.24 **CertEx v3.01e**
Kizárólag a két tintával szíjazott másolat tekinthető hitelesnek!