

PCO 11/13

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: (5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(trifluoromethylthio)1H-pyrazole-3-carbonitrile	≤ 1.0%	0.0201%
Impurity B: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(trifluoromethylsulfanyl)-1H-pyrazole-3-carbonitrile	≤ 1.0%	0.0374%
Single unknown impurity:	≤ 1.0%	
Moisture	≤ 4.0%	0.0094%
Uniformity of Dosage Units: (Acceptance Value)	Not more than 2.0%	0.0722%
Microbial Purity*	Conforms to Ph. Eur. 2.9.40 Acceptance Value ≤ 15.0 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>	0.09%
		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. 31116/3/12, 2204/12.

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

Checked By: [Signature] **Date:** 15/02/13
Quality Assurance (Signature)
Approved By: [Signature] **Date:** 15/02/13
Qualified Person (Signature)
Qualified Person (Print Name): BACEES DIJK

Directors: Michael J Burke, Chanelle McCoy, Michael J Burke, Hilary Burke

Registered No: 101675

Diszjós: PN-ZA14000589 Vevő: Alpha- Vet Kft File név: PN00007382 Egyedi sorszám: PN0000071645 85 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0111/13
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2014.07.04 **CertEx v.3.03**

