PCO 12/13

chanelle
PHARMACEUTICALS
MANUFACTURING LTD

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# CERTIFICATE OF ANALYSIS / CONFORMANCE

| | | | |
|---|---|---|---|
| **Product:** | **Controline 134mg** | | |
| **Customer:** | **Pfizer Animal Health** | **Man Date:** | **12 / 2012** |
| **Livery:** | **Hungary/Poland** | **Expiry Date:** | **11 / 2014** |
| **Batch No.:** | **28099/2M47** | | |

| 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<br>134mg ± 5% (Limits 127.3 – 140.7mg) | 129.373mg |
| Assay: Butylhydroxyanisole | 90 – 110% of the label claim<br>0.268mg ± 10% (Limits 0.241 – 0.295mg) | 0.259mg |
| Assay: Butylhydroxytoluene | 90 – 110% of the label claim<br>0.134mg ± 10% (Limits 0.121 – 0.147mg) | 0.127mg |
| Impurity A:<br>(5-amino-1-(2,6-dichloro-4-)trifluoromethyl)phenyl)-4-(trifluoromethythio)1H-pyrazole-3-carbonitrile | ≤ 1.0% | 0.0215% |
| Impurity B:<br>5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(trifluoromethylsulfonyl)-1H-pyrazole-3-carbonitrile | ≤ 1.0% | 0.040% |
| Single unknown impurity:: | ≤ 1.0% | 0.0098% |
| Total impurities: | ≤ 4.0% | 0.077% |
| Moisture | Not more than 2.0% | 0.12% |
| Uniformity of Dosage Units:<br>(Acceptance Value) | Conforms to Ph. Eur. 2.9.40<br>Acceptance Value ≤ 15.0 | 3.8 |
| Microbial Purity* | Conform to Ph. Eur. 5.1.4<br>NMT $10^2$ bacteria, NMT $10^1$ fungi per gram<br>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. 3115/3/12 , 2203/12

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)

DARREN DALY
Qualified Person (Print Name)