



PFIZER PGM  
ZONE INDUSTRIELLE  
29 ROUTE DES INDUSTRIES  
37530 POCE SUR CISSE - FRANCE  
TEL 33 2 47 23 77 78  
FAX 33 2 47 23 79 80

## Certificate of Analysis

Material Name: DRAXXIN 50ML B1 HUN/LTU/EST  
Material Code: 0671HUN

Lot Number: A332402  
Specification: 00RS65327(04-2003)-50ML  
Date of Manufacture: MAR. 27, 2013  
Expiration Date: FEB-2016

| TEST  | Limit  | Result       |
|---|--|--------------|
| Appearance  | Clear, colorless to slightly yellow solution essentially free from foreign matter.           | MEETS TEST   |
| Particulate Contamination: Visible Particles      | Vial is essentially free of visible foreign matter.  | MEETS TEST   |
| Monothioglycerol                                  | 90% to 110% of label claim   | 100 %        |
| pH  | 5.1 to 5.7   | 5.4          |
| Sterility   | MEETS TEST   | MEETS TEST   |
| Assay (HPLC) (CP-472,295+CP-547,272)              | 95% to 105% of label claim   | 100 %        |
| Identity CP-472,295 (HPLC)                        | Peak retention time of CP-472,295 is the same as that of the identity standard.              | MEETS TEST   |
| Identity CP-547,272 (HPLC)                        | Peak retention time of CP-547,272 is the same as that of the identity standard.              | MEETS TEST   |
| %CP-547,272 Ratio Relative to Total Tulathromycin | 8% to 13%  | 11 %         |
| Specified Degradation Products CP-60,300          | 0.8% maximum   | 0.0 %        |
| Specified Degradation Products CP-651,595         | 0.8% maximum   | 0.0 %        |
| Unspecified Degradation Products                  | <1.0% each   | 0.0 %        |
| Total Degradation Products                        | 2.0% maximum   | 0.0 %        |
| Identity (TLC)                                    | Mobilities (Rf) of CP-472,295 and CP-547,272 are the same as those of the identity standard. | MEETS TEST   |
| Extractable volume                                | MEETS TEST   | MEETS TEST   |
| Bacterial endotoxins                              | 200 IU/ml maximum  | <= 100 IU/ml |

This product was manufactured in accordance with current GMP and with the approved registration dossier of the product.

For Hungary only :

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP

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Node: emaedcs059

Instance Name: LICFR6P

Diszpó: PN-ZA14000034 Vevő: TolnAgro Kft 7100 File név: PN00007507 Egyedi sorszám: PN000007031 4 másolat  
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0282/13  
Az eredetivel megegyező elektronikus másolat a(z):  
Dr. Nagy Edith min.bizt.gyógyszerész által küldve. Nyomtatás dátuma: 2014.01.13 CertEx v 3.02



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requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of Hungary or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

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### QUALIFIED PERSON ASSESSMENT.

Electronic Signature: Beatrice CAZEAUX Lot Release Local Timestamp: 24-JUN-2013 10:18:39

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|  |                                     |                              |                             |   |         |
|--|-------------------------------------|------------------------------|-----------------------------|---|---------|
| Diszpó: PN-ZA14000034                              | Vevő: TolnAgro Kft 7100             | File név: PN00007507         | Egyedi sorszám: PN000007031 | 4 | másolat |
| Szállító: Zoetis Hungary Kft.                      |                                     | Oldal/Lap 2 / 2              | Anyaglap: PN0282/13         |   |         |
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| Dr. Nagy Edith                                     | min.bizt.gyógyszerész által küldve. |                              |                             |   |         |