



## Certificate of Analysis

Material Name: DECTOMAX CATTLE 500ML  
Material Code: DECTO INJ\_HUN\_500

Lot Number: 20454018DP\$ENVOI12  
Specification: 00RS06646-2(02-1996)-500ML  
Date of Manufacture: APR. 01, 2012  
Expiration Date: APR-2015

| TEST                              | Limit  | Result       |
|-----------------------------------|--|--------------|
| Appearance                        | Clear, colorless to pale yellow solution conforming to parenteral standards, in amber glass vials. | MEETS TEST   |
| Colour (400nm)                    | MAX 0.2  | 0.1          |
| Water content (KF)                | MAX 0.05%  | 0.01 %       |
| Butylhydroxyanisol content        | 50-125ppm  | 98 ppm       |
| Total degradation (HPLC)          | MAX 2%   | 1 %          |
| Extractable volume                | MIN 500.0ml  | 509.8 ml     |
| Sterility                         | MEETS TEST   | MEETS TEST   |
| Bacterial endotoxins              | <=165IU/ml   | <= 165 IU/ml |
| Doramectine identification (HPLC) | MEETS TEST   | MEETS TEST   |
| Doramectine content (HPLC)        | 9.5-10.5mg/ml  | 9.6 mg/ml    |
| Density (20°C)                    | 0.902-0.912g/ml  | 0.908 g/ml   |

This product was tested by Pfizer PGM Amboise (France) Quality Operations Laboratory and the results obtained show compliance with the product release specifications.

The temperature was not monitored during the transportation of this batch. The absence of temperature data led to a complete analysis of the batch and the results were found conform which confirms that there was no impact on the quality of the product.

Deviation: none

## CERTIFICATE OF RELEASE

This is to confirm that the batch referenced above is released for sale in accordance with the Marketing Authorisation and Council Directive 2001/82/EC.



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For markets:  
Hungary, Romania, Bulgaria, Slovenia, Albania, Bosnia, Belarus, Croatia.

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QUALIFIED PERSON ASSESSMENT.

Electronic Signature: Beatrice CAZEAUX Lot Release Local Timestamp: 11-OCT-2013 09:43:03

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Node: empedca059

Instance Name: LICFRBP

|  |                                     |                              |                             |      |         |
|--|-------------------------------------|------------------------------|-----------------------------|------|---------|
| Diszpó: PN-ZA14000282                              | Vevő: TolnAgro Kft 7100             | File név: PN00007781         | Egyedi sorszám: PN000007088 | 2    | másolat |
| Szállító: Zoetis Hungary Kft.                      |                                     | Oldal/Lap 2 / 2              | Anyaglap: PN0034/14         |      |         |
| Az eredetivel megegyező elektronikus másolat a(z): |                                     |                              |                             |      |         |
| Dr. Nagy Edith                                     | min.bizt.gyógyszerész által küldve. | Nyomtatás dátuma: 2014.03.26 | CertEx v                    | 3.02 |         |