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Certificate of Analysis

Material Name: DRAXXIN 100ML B1 HUN/EST/LTU
Material Code: 0672HUN

Lot Number: A332902
Specification: 00RS65327(04-2003)-100ML
Date of Manufacture: MAR. 25, 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	99 %
pH	5.1 to 5.7	5.4
Sterility	MEETS TEST	MEETS TEST
Identity (TLC)	Mobilities (Rf) of CP-472,295 and CP-547,272 are the same as those of the identity standard.	MEETS TEST
Assay (HPLC) (CP-472,295+CP-547,272)	95% to 105% of label claim	99 %
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 %
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

Page 1 of 2

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Node: emaedca058

Instance Name: LICRFRP

Diszpó: PN-ZA13001201 Vevő: Alpha-Vet 8000 File név: PN00007508 Egyedi sorszám: PN000070157 11 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0283/13
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2013.12.18
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v 3.02

