



s.p.® veterinaria, s.a.

Ctra. Reus-Vinyols, km. 4,1
Apartado 60
43330 - RIUDOMS (Tarragona)
Tel. 977 850 170*
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www.spveterinaria.com

DEPARTAMENTO TECNICO
TECHNICAL DEPARTMENT

SECCION DE CONTROL DE CALIDAD
QUALITY CONTROL SECTION

PRODUCTO
PRODUCT

COLMYC 100 MG/ML

LOTE No. 14/4
BATCH No.

FECHA DE FABRICACIÓN NOV 2014
MANUFACTURING DATE

CERTIFICADO DE ANALISIS / ANALYSIS CERTIFICATE

TEST	LIMITS AND REFERENCE STANDARD	RESULTS
APPEARANCE	Yellow liquid (EP 2.2.1 and 2.2.2)	Yellow liquid
RELATIVE DENSITY	1.030 – 1.050 g/ml (EP 2.2.5)	1.033 g/ml
REFRACTIVE INDEX	1.3600 – 1.3700 (EP 2.2.6)	1.3620
pH	11 - 14 (EP 2.2.3)	12.20
TRANSPARENCY	Transparent (In-house method, visual)	Transparent
PARTICLES	Absence (In-house method, visual)	Absence
APPARENT HOMOGENEITY	Homogeneous (In-house method, visual)	Homogeneous
QUANTITATIVE ASSAY		
- Enrofloxacin	9.50 – 10.50 % (w/v) (EP 2.2.29)	10.12 %
- Alcohol N-Butylic	2.70 – 3.30 % (w/v)	2.75 %
MICROBIOLOGICAL TESTS		
- Sterility	- Sterile (EP 2.6.1)	Sterile
- Pyrogens	- Complies (EP 2.6.8)	Complies
OTHERS (Packing)		
- Contents (min. fill volume)	100 ml Vial: 100 – 102 ml (In-house meth.)	100.5 ml
- Airtight control	Airtight (In-house method)	Airtight
- Container Alterations	None (In-house method)	None
REMARKS	Analysis date: 18 NOV 2014 Expiry date: NOV 2017 Reference: 1401313 PASS	Riudoms, 18 MAY 2015

*Note: EP stands for European Pharmacopoeia

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KERESKEDELMI CÉLRA
FELEZÁRADITVA
DR LENGYEL TAMÁS
minőségügyi felelős

N.I.F. A-43056795. Inscrita Reg. Merc. de Tarragona, fecha 10.05.84, tomo 301, libro 227, Sección 3ª, folio 108, hoja 5.139, inscripción 1ª



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RELEASE FOR SALE TO MARKET

1. Name of the product.

COLMYC 100 mg/ml

2. Importing country.

Hungary

3. Marketing Authorisation Number in the importing country.

2728/2/10 MgSzH ÁTI (100 ml)

4. Strength/Potency.

Enrofloxacin 100 mg/ml

5. Dosage form (pharmaceutical form).

Injectable solution.

6. Package size and type

100 ml.

7. Batch number

14/4

8. Date of manufacture

November 2014

9. Expiry date

November 2017

10. Name and address of manufacturer

S.P. VETERINARIA, S.A.
Riudoms (Tarragona) - Spain

11. Number of Manufacturing Authorization/Licence or Certificate of GMP Compliance.

4274-E

12. Results of analysis.

See attached Certificate of Analysis.

13. Comments/remarks

No applicable.

14. Certification statement.

We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

15. Person authorising the batch release

Dr. Teresa Sanz - Technical Director

16. Signature of the person authorising the batch release



17. Date of signature

22th May 2015