



s.p.[®] veterinaria, s.a.

Ctra. Reus-Vinyols, km. 4,1
Apartado 60
43330 - RIUDOMS (Tarragona)
Tel. 977 850 170
Fax. 977 850 405
www.spveterinaria.com

DEPARTAMENTO TECNICO
TECHNICAL DEPARTMENT

SECCION DE CONTROL DE CALIDAD
QUALITY CONTROL SECTION

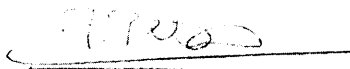
PRODUCTO
PRODUCT

COLMYC 100 MG/ML


LOTE No. 14/1
BATCH No.

FECHA DE FABRICACIÓN APR 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)	1.032 g/ml
REFRACTIVE INDEX	1.3600 – 1.3700 (EP 2.2.6)	1.3621
pH	11 - 14 (EP 2.2.3)	12.34
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 - Alcohol N-Butylic	9.50 – 10.50 % (w/v) (EP 2.2.29) 2.70 – 3.30 % (w/v)	9.88 % 2.72 %
MICROBIOLOGICAL TESTS - Sterility - Pyrogens	- Sterile (EP 2.6.1) - Complies (EP 2.6.8)	Sterile Complies
OTHERS (Packing) - Contents (min. fill volume) - Airtight control - Container Alterations	100 ml Vial: 100 – 102 ml (In-house meth.) Airtight (In-house method) None (In-house method)	100.30 ml Airtight None
REMARKS	Analysis date: 28 APR 2014 Expiry date: APR 2017 Reference: 1400416 PASS	Riudoms, 15 APR 2014 

*Note: EP stands for European Pharmacopoeia


KERESKEDELMI CÉLRA
FELSZABADÍTVÁ

DR LENGYEL TAMÁS
minőségügyi felelős

s.p. veterinaria, s.a.

Ctra. Reus-Vinyols, Km. 4,1
Apartado Correos nº 60
43330 RIUDOMS (Tarragona)
Tel. 977 850 170



s.p.[®] veterinaria, s.a.

Ctra. Reus-Vinyols, km. 4,1
Apartado 60
43330 - RIUDOMS (Tarragona)
Tel. 977 850 170
Fax. 977 850 405
www.spveterinaria.com

BATCH RELEASE CERTIFICATE

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

14/1

8. Date of manufacture

April 2014

9. Expiry date

April 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



s.p.[®] veterinaria, s.a.

Ctra. Reus-Vinyols, km. 4,1
Apartado 60
43330 - RIUDOMS (Tarragona)
Tel. 977 850 170*
Fax. 977 850 405
www.spveterinaria.com

12. Results of analysis.

See attached Certificate of Analysis.

13. Comments/remarks

No applicable.


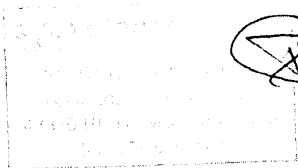
14. Certification statement.

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

15th May 2014