



s.p.® veterinaria, s.a.

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DEPARTAMENTO TECNICO
TECHNICAL DEPARTMENT

SECCION DE CONTROL DE CALIDAD
QUALITY CONTROL SECTION


PRODUCTO
PRODUCT

COLMYC 100 MG/ML


LOTE No. 19/1
BATCH No.

FECHA DE FABRICACIÓN MAY 2019
MANUFACTURING DATE

CERTIFICADO DE ANALISIS / ANALYSIS CERTIFICATE

PRUEBA	LÍMITES Y REFERENCIA	RESULTADO
APPEARANCE	Yellow liquid (EP 2.2.1 y 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)	1.3617
pH	11 - 14 (EP 2.2.3)	11.54
BIOBURDEN	< 10 UFC/ 100 ml	Complies
APPARENT HOMOGENEITY	Homogeneous (In-house method, visual)	Homogeneous
QUANTITATIVE ASSAY - Enrofloxacin Sustancias relacionadas: - Ciprofloxacin - Impurity RRT 2.05 - Individual impurity - Total impurities - Butyl Alcohol	9.5 – 10.5 % (p/v) (EP 2.2.29) < 0.05 % (p/v) (EP 2.2.29) < 0.02 % (p/v) (EP 2.2.29) < 0.01 % (p/v) (EP 2.2.29) < 0.07 % (p/v) (EP 2.2.29) 2.7 – 3.3 % (p/v)	10.01 % 0.004 % ND 0.007 0.015 % 2.95 %
MICROBIOLOGICAL TESTS - Sterility	- Sterile (EP 2.6.1)	Sterile
OTHERS (Packing) - Contents (min. fill volume) - Airtight control - Container Alterations	250 ml vial: 250 – 255 ml (In-house meth.) 100 ml vial: 100 – 102 ml (In-house meth.) Airtight (In-house method) None (In-house method)	----- 101 ml Airtight None
REMARKS	Analysis date: 31 MAY 2019 Expiry date: MAY 2022 Reference: 1900766 PASS	Riudoms, 10 SEP 2019 

*Nota: EP stands for European Pharmacopoeia


KERESKEDELMI CELLA
FELSZABADÍTVA

DR LENGYEL TAMÁS
minőségügyi felelős

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