

Certificate of Compliance

KRKA, d.d., Novo mesto

Date: 07.03.2016

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Name of Product: 756212 CALFOSET 100 ml solution for injection for veterinary use	
Dosage form: Solution for injection	Package size: 1
Strenght/Potency (ammount per unit dose):	
Batch No. final product: A62053	Customer's batch No.:
Batch No. bulk: A61948	-
Date of manufacture: 12.2015	Expiry date: 12.2018
Importing country - Marketing Authorisation No.: RO - 110325	
Name and address of manufacturing site for bulk: KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenia	Manufacturing Authorisation No: 800-24/2014-13
	Certificate of GMP compliance: 401-15/2014-4
Name and address of manufacturing site for finished product: KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenia	Manufacturing Authorisation No: 800-24/2014-13
	Certificate of GMP compliance: 401-15/2014-4
Name and address of quality control: KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenia	Manufacturing Authorisation No: 800-19/2013-5
	Certificate of GMP compliance: 401-15/2014-4

Quantity of Batch: **2.992 PC**

Delivered quantity: **14 PC**

According to Specification: **SRA0436**

Certification statement:

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 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.

Date of release:
11.02.2016

Qualified Person for Batch Release:
Brigita Pucelj

Quality Management Division
KRKA, d.d. Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Certificate of Analysis

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Name of Product: 756212 CALFOSET 100 ml solution for injection for veterinary use	
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Batch No. bulk: A61948	
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Characteristic	Specification	Results
Appearance	Clear, slightly yellowish solution, practically without particles	Complies
Extractable volume	Not less than 100 ml (250 ml)	Complies
Identification of calcium	Complies with the test in the analytical procedure.	Complies
Identification of magnesium	Complies with the test in the analytical procedure.	Complies
Identification of chlorides	Complies with the test in the analytical procedure.	Complies
Identification of phosphorus	Assay is at the same time identification.	Complies
Particulate particles: Visible particle	Practically free from particles.	Complies
pH	3.5 - 4.5	4.2
Content of calcium	Min. 4.14 g/100 ml	4.58
Content of magnesium	Min. 0.45 g/100 ml	0.50
Content of phosphorus	Min. 1.08 g/100 ml	1.31
Sterility	The solution for injection must be sterile.	Complies
LAL: Bacterial endotoxins: Less than	5 i.u./ml	< 0.63

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