

Certificate of Compliance



KRKA, d.d., Novo mesto

Date: 19.02.2018

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Name of Product: 763165 CALFOSET injection 100 ml for veterinary use	
Dosage form: Solution for injection	Package size: 1
Strength/Potency (amount per unit dose):	
Batch No. final product: A66133	Customer's batch No.:
Batch No. bulk: A66017	-
Date of manufacture: 07.2017	Expiry date: 07.2020
Importing country - Marketing Authorisation No.: HR - UP/I-322-05/12-01/383	
Name and address of manufacturing site for bulk: KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenia	Manufacturing Authorisation No: 800-14/2017-4
	GMP certificate No: 401-15/2016-6
Name and address of manufacturing site for finished product: KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenia	Manufacturing Authorisation No: 800-14/2017-4
	GMP certificate No: 401-15/2016-6
Name and address of quality control: KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenia	Manufacturing Authorisation No: 800-14/2017-4
	GMP certificate No: 401-15/2016-6

Quantity of Batch: **5.091 PC**

Delivered quantity: **1.000 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:

24.07.2017

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



KRKA, d.d., Novo mesto

Date: 19.02.2018

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Name of Product: 763165 CALFOSET injection 100 ml for veterinary use	
Dosage form: Solution for injection	Package size: 1
Strength/Potency (amount per unit dose):	
Batch No. final product: A66133	Customer's batch No.: -
Batch No. bulk: A66017	
Date of manufacture: 07.2017	Expiry date: 07.2020

Characteristic	Specification	Results
Appearance	Clear, slightly yellow solution, without visible foreign particles	Complies
Particulate particles: Visible particle	Practically free from 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
pH	3.5 - 4.5	4.1
Content of calcium	Min. 4.14 g/100 ml	4.43
Content of magnesium	Min. 0.45 g/100 ml	0.52
Content of phosphorus	Min. 1.08 g/100 ml	1.24
Sterility	The solution for injection must be sterile.	Complies
LAL: Bacterial endotoxins: Less than	5 i.u./ml	< 0.63

Date of release:
24.07.2017

Qualified Person for Batch Release:
Brigita Pucelj

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KRKA, d.d. Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto, Slovenia