Certificate of Compliance



KRKA, d.d., Novo mesto

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Name of Product: 782580 ECOCID S powder for vete	rinary use
Dosage form: powder	Package size: 1X2.5 kg
Strength/Potency (amount per unit dose):	
Batch No. final product: Z80828	Customer's batch No.;
Batch No. bulk: Z80643	-
Date of manufacture: 06.2018	Expiry date: 06.2021
Importing country - Marketing Authorisation No.: RO - 184BIO/03/12.24	
Name and address of manufacturing site for bulk: KRKA, d.d., Novo mesto Šmarješka cesta 6 Novo mesto, 8501, Slovenia	Manufacturing Authorisation No: 800-43/2017-10
	GMP certificate No: 401-10/2015-5
Name and address of manufacturing site for finished product: KRKA, d.d., Novo mesto Šmarješka cesta 6 Novo mesto, 8501, Slovenia	Manufacturing Authorisation No: 800-43/2017-10
	GMP certificate No: 401-10/2015-5
Name and address of quality control: KRKA, d.d., Novo mesto Šmarješka cesta 6 Novo mesto, 8501, Slovenia	Manufacturing Authorisation No: 800-43/2017-10
	GMP certificate No:

Quantity of Batch: 1.008 PC

According to Specification: SRA0597

Delivered quantity: 1 PC

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 where reviewed and found to be in compliance with GMP.

Date of release: 28.06.2018 Qualified Person for Batch Release: Andreja Senica

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

Certificate of Analysis



Date: 02.07.2018

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Name of Product: 782580 ECOCID S powder for veterinary use		
Dosage form: powder	Package size: 1X2.5 kg	
Strength/Potency (amount per unit dose):		
Batch No. final product: Z80828	Customer's batch No.:	
Batch No. bulk: Z80643	•	
Date of manufacture: 06.2018	Expiry date: 06.2021	

Characteristic	Specification	Results	
Appearance	Pink-grey granulate, odour of lemon	Complies	
Appearance of solution	Solution is clear, pink coloured and without	Complies	
	undisolved particles		
H	2.0 - 2.7	2.5	
Assay of available oxygen	Min. 9.5 %	10.7	

Date of release: 28.06.2018

Qualified Person for Batch Release: Andreja Senica

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