

Certificate of Analysis



KRKA, d.d., Novo mesto

Date: 27.09.2018

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Name of Product: 783028 ECOCID S powder for veterinary use	
Dosage form: powder	Package size: 1X2.5 kg
Strength/Potency (amount per unit dose):	
Batch No. final product: Z80341	Customer's batch No.: -
Batch No. bulk: Z80032	
Date of manufacture: 04.2018	Expiry date: 04.2023

Characteristic	Specification	Results
Appearance	Pink-grey granulate, odour of lemon	Complies
Appearance of solution	Solution is clear, pink coloured and without undissolved particles	Complies
pH	2.0 - 2.7	2.5
Assay of available oxygen	Min. 9.5 %	10.9

Date of release:
22.05.2018

Qualified Person for Batch Release:
Andreja Senica

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



KRKA, d.d., Novo mesto

Date: 27.09.2018

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Certificate of Compliance

Name of Product: 783028 ECOCID S powder for veterinary use	
Dosage form: powder	Package size: 1X2.5 kg
Strength/Potency (amount per unit dose):	
Batch No. final product: Z80341	Customer's batch No.:
Batch No. bulk: Z80032	-
Date of manufacture: 04.2018	Expiry date: 04.2023
Importing country - Marketing Authorisation No.: HR - UP/I-543-04/11-05/196	
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: 450-35/2017-1

Quantity of Batch: **696 PC**

Delivered quantity: **300 PC**

According to Specification: **SRA0597**

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:
22.05.2018

Qualified Person for Batch Release:
Andreja Senica

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8501 Novo mesto, Slovenia