Certificate of Compliance



Date: 14.11.2017 Page: 1/2

| Name of Product: 782958 ECOCID S powder for vete | |
|--|---|
| Dosage form: Powder | Package size: 1 |
| Strenght/Potency (ammount per unit dose): | |
| Batch No. final product: Z78183 | Customer's batch No.: |
| Batch No. bulk: Z78162 | •2 |
| Date of manufacture: 10.2017 | Expiry date: 10.2020 |
| Importing country - Marketing Authorisation No.: RO - 184BIO/03/12.24 Name and address of manufacturing site for bulk: KRKA, d.d., Novo mesto | Manufacturing Authorisation No: |
| Šmarješka cesta 6, 8501 Novo mesto, Slovenia | |
| | Certificate of GMP compliance: 401-10/2015-5 |
| Name and address of manufacturing site for finished product: KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenia | Manufacturing Authorisation No: 800-43/2017-10 |
| | Certificate of GMP compliance: 401-10/2015-5 |
| 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 |
| | Certificate of GMP compliance: 450-35/2017-1 |
| | |

Quantity of Batch: 497 PC

PC

Acording 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 where reviewed and found to be in compliance with GMP.

Delivered quantity: 1 PC

Date of release: 08.11.2017

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: 14.11.2017 Page: 2/2

| Name of Product: 782958 ECOCID S powder for veterinary use | | |
|--|-----------------------|--|
| Dosage form: Powder | Package size: 1 | |
| Strenght/Potency (ammount per unit dose): | | |
| Batch No. final product: Z78183 | Customer's batch No.: | |
| Batch No. bulk: Z78162 | | |
| Date of manufacture: 10.2017 | Expiry date: 10.2020 | |

| Characteristic | Specification | Results |
|---------------------------|--|----------|
| Appearance | Pink-grey granulate, odour of lemon | Complies |
| Appearance of solution | Solution is clear, pink coloured and without undisolved particles | Complies |
| pH | 2.0 - 2.7 | 2.6 |
| Assay of available oxygen | Min. 9.5 % | 11.1 |

Date of release: 08.11.2017

Qualified Person for Batch Release: Andreja Senica

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