

## Certificate of Compliance



KRKA, d.d., Novo mesto

Date: 27.03.2017

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|  |  |
|--|--|
| Name of Product: <b>782959 ECOCID S powder for veterinary use</b>  |  |
| Dosage form: <b>Powder</b>   | Package size: <b>25</b>                                |
| Strength/Potency (ammount per unit dose):  |  |
| Batch No. final product: <b>Z75475</b>   | Customer's batch No.:                                  |
| Batch No. bulk: <b>Z75471</b>  | -  |
| Date of manufacture: <b>12.2016</b>  | Expiry date: <b>12.2019</b>                            |
| Importing country - Marketing Authorisation No.:<br><b>RO - 184BIO/03/12.24</b>  |  |
| Name and address of manufacturing site for bulk:<br><b>KRKA, d.d., Novo mesto</b><br><b>Šmarješka cesta 6, 8501</b><br><b>Novo mesto, Slovenia</b>             | Manufacturing Authorisation No:<br><b>800-4/2016-4</b> |
|  | Certificate of GMP compliance:<br><b>401-10/2015-5</b> |
| Name and address of manufacturing site for finished product:<br><b>KRKA, d.d., Novo mesto</b><br><b>Šmarješka cesta 6, 8501</b><br><b>Novo mesto, Slovenia</b> | Manufacturing Authorisation No:<br><b>800-4/2016-4</b> |
|  | Certificate of GMP compliance:<br><b>401-10/2015-5</b> |
| Name and address of quality control:<br><b>KRKA, d.d., Novo mesto</b><br><b>Šmarješka cesta 6, 8501</b><br><b>Novo mesto, Slovenia</b>                         | Manufacturing Authorisation No:<br><b>800-4/2016-4</b> |
|  | Certificate of GMP compliance:<br><b>401-7/2016-4</b>  |

Quantity of Batch: **499 PC**

Delivered quantity: **25 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:  
12.01.2017

Qualified Person for Batch Release:  
Milena Žigante

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

## Certificate of Analysis



KRKA, d.d., Novo mesto

Date: 27.03.2017

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|   |                             |
|---|-----------------------------|
| Name of Product: <b>782959 ECOCID S powder for veterinary use</b> |                             |
| Dosage form: <b>Powder</b>  | Package size: <b>25</b>     |
| Strenght/Potency (ammount per unit dose):                         |                             |
| Batch No. final product: <b>Z75475</b>                            | Customer's batch No.:       |
| Batch No. bulk: <b>Z75471</b>                                     | -                           |
| Date of manufacture: <b>12.2016</b>                               | Expiry date: <b>12.2019</b> |

| 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 %   | 11.1     |

Date of release:  
12.01.2017

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