

## Certificate of Compliance



KRKA, d.d., Novo mesto

Date: 04.05.2015

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Name of Product: <b>774653 FLORON 300 mg/ml solution for injections for veterinary use</b>	
Dosage form: <b>Sterile solutions 100mL</b>	Package size: <b>1</b>
Strength/Potency (amount per unit dose): <b>300mg/ml</b>	
Batch No. final product: <b>A60340</b>	Customer's batch No.:
Batch No. bulk: <b>A60263</b>	-
Date of manufacture: <b>02.2015</b>	Expiry date: <b>02.2018</b>
Importing country - Marketing Authorisation No.: <b>BG - No 0022-2215</b>	
Name and address of manufacturing site for bulk: <b>KRKA, d.d., Novo mesto</b> <b>Šmarješka cesta 6, 8501</b> <b>Novo mesto, Slovenia</b>	Manufacturing Authorisation No: <b>800-24/2014-13</b> Certificate of GMP compliance: <b>401-15/2014-4</b>
Name and address of manufacturing site for finished product: <b>KRKA, d.d., Novo mesto</b> <b>Šmarješka cesta 6, 8501</b> <b>Novo mesto, Slovenia</b>	Manufacturing Authorisation No: <b>800-24/2014-13</b> Certificate of GMP compliance: <b>401-15/2014-4</b>
Name and address of quality control: <b>KRKA, d.d., Novo mesto</b> <b>Šmarješka cesta 6, 8501</b> <b>Novo mesto, Slovenia</b>	Manufacturing Authorisation No: <b>800-19/2013-5</b> Certificate of GMP compliance: <b>401-15/2014-4</b>

Quantity of Batch: **500 PC**

According to Specification: **SRA0695**

### 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:  
20.03.2015

Qualified Person for Batch Release:  
Majda Šenica *Yleno*

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



## Certificate of Analysis



KRKA, d.d., Novo mesto

Date: 04.05.2015

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Name of Product: <b>774653 FLORON 300 mg/ml solution for injections for veterinary use</b>	
Dosage form: <b>Sterile solutions 100mL</b>	Package size: <b>1</b>
Strength/Potency (ammount per unit dose): <b>300mg/ml</b>	
Batch No. final product: <b>A60340</b>	Customer's batch No.: -
Batch No. bulk: <b>A60263</b>	
Date of manufacture: <b>02.2015</b>	Expiry date: <b>02.2018</b>

Characteristic	Specification	Results
Appearance	Light yellow to yellow clear viscose liquid	Complies
Extractable volume	Min. 100 ml	102
Identification of florfenicol	Assay is at the same time identification.	Complies
Related substances - florfenicol amin	Max. 1.0 %	<= 0.30
Related substances - other individual	Max. 1.0 %	<= 0.30
Related substances - other total	Max. 2.0 %	<= 0.30
Content of florfenicol	95.0 - 105.0 % of stated amount	98.8
Sterility	The solution for injection must be sterile.	Complies
LAL: Bacterial endotoxins: Less than	0.125 I.U./mg	< 0.042

Date of release:  
20.03.2015

Qualified Person for Batch Release:  
Majda Šenica *g. Senica*

Quality Management Division  
KRKA, d.d. Novo mesto,  
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