Certificate of Compliance

KRKA, d.d., Novo mesto

Date: 24.06.2022

Name of Product: 7F4474 **ATAXXA 1250 mg/250 mg spot on solution for veterinary use**	
Dosage form: **spot-on solution**	Package size: **1X2.5 ml**
Strength/Potency (amount per unit dose): **100 mg/500 mg/ml**	
Batch No. final product: **Z91955**	Customer's batch No.: -
Batch No. bulk: **Z91949**	
Date of manufacture: **01.2022**	Expiry date: **01.2025**
Importing country - Marketing Authorisation No.: **CZ - 96/092/15-C; PL - 2513/16 SK - 96/064/DC/15-S**	
Name and address of manufacturing site for bulk: **KRKA, tovarna zdravil, d.d., Novo mesto Povhova ulica 5 Novo mesto, 8501, Slovenia**	Manufacturing Authorisation No: **800-13/2018-6**
	GMP certificate No: **401-6/2021-3**
Name and address of manufacturing site for finished product: **KRKA, tovarna zdravil, d.d., Novo mesto Povhova ulica 5 Novo mesto, 8501, Slovenia**	Manufacturing Authorisation No: **800-13/2018-6**
	GMP certificate No: **401-6/2021-3**
Name and address of quality control: **KRKA, d.d., Novo mesto Šmarješka cesta 6 Novo mesto, 8501, Slovenia**	Manufacturing Authorisation No: **800-13/2018-6**
	GMP certificate No: **401-6/2021-5**

Quantity of Batch: **15.125 PC**

According to Specification: **DPSPEC006252/3**

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:
01.02.2022

Qualified Person for Batch Release:
Milena Žigante

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

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KRKA,
tovarna zdravil, d.d.,
Novo mesto

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