

Norbrook Laboratories Ltd
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Northern Ireland

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Name of Product:	Apelka 5 mg/ml Losung zum Eingeben fur Katzen [Boehringer Austria, Czech & Hungary]			99007-DP1-02 (945)
Batch Number	Quantity	Manufacture Date	Expiry Date	Packaging
9391-90A	10,440	September 2019	September 2021	30 ml Plastic Bottle

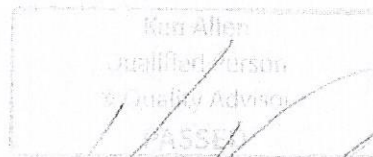
Analytical	Results	Specifications
Appearance	Conforms	An off-white to light yellow opaque solution
Thiamazole	0.502 % w/v 5.02 mg/ml Confirmed	0.475 to 0.525% w/v 4.75 to 5.25 mg/ml Identification by HPLC: Confirmed
Thiamazole Related Substances	0.0 % 0.0 %	Identification by GC: Confirmed Each individual: NMT 1.0% of active Total: NMT 1.5% of active
pH	4.2	3.8 to 4.5
Sodium Benzoate Content	0.151 %w/v Confirmed	0.135 to 0.165% w/v Identification by HPLC: Confirmed
Viscosity	67 cPs	40 to 90 cPs
Uniformity of Mass of Delivered Dose	Complies	Complies with current Ph. Eur. 2.9.27 for dose levels 0.25ml and 1.0ml
Microbial Quality	Not Applicable	Complies with Ph. Eur. 5.1.4
Volume of Fill	119 % (35.4 ml)	Not less than 100%

*Non-routine test. 1 batch per annum or every tenth batch, whichever is more frequent

I hereby certify that the above information is authentic and accurate in so far that the specification information is available to us and we confirm that our scientific findings are true. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site (Manufacturing Authorisation Number: ManA 2000) in full compliance with GMP requirements and in accordance with the specification provided to us. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Prepared By:
Date:

Mahira Begum
25-October-2019



25 OCT 2019



Batch Release Statement

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Product Name: Apelka 5 mg/ml Losung zum
Eingeben fur Katzen

Batch Number: 9391-90A

Unit Pack Size: 30 ml

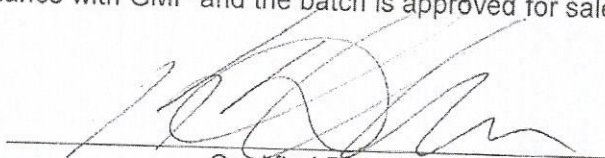
Country: Boehringer Austria, Czech &
Hungary

Quantity of Packed Units: 10,440

Expiry Date: September 2021

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and the requirements of the Marketing Authorisation(s) of the destination country/countries.

The batch processing, packaging and analytical records have been reviewed and found to be in compliance with GMP and the batch is approved for sale.

Signed:  Date: 29.10.2019

Qualified Person