

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
9431-93A	10,536	October 2019	October 2021	30 ml Plastic Bottle

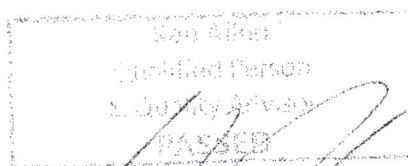
Analytical	Results	Specifications
Appearance	Conforms	An off-white to light yellow opaque solution
Thiamazole	0.496 % w/v 4.96 mg/ml Confirmed Confirmed	0.475 to 0.525% w/v 4.75 to 5.25 mg/ml Identification by HPLC: Confirmed Identification by GC: Confirmed
Thiamazole Related Substances	0.0 % 0.0 %	Each individual: NMT 1.0% of active Total: NMT 1.5% of active
pH	4.1	3.8 to 4.5
Sodium Benzoate Content	0.148 %w/v Confirmed	0.135 to 0.165% w/v Identification by HPLC: Confirmed
Viscosity	70 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	118 % (35.3 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:


23-November-2019



22 NOV 2019



Batch Release Statement

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Product Name: Apelka 5 mg/ml Losung Zum
Eingeben Fur Katzen

Batch Number: 9431-93A

Unit Pack Size: 30 ml Plastic Bottle

Country: Boehringer Austria, Czech &
Hungary

Quantity of Packed Units: 10,536

Expiry Date: October 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: _____

Qualified Person

Date: _____

22.11.2019