

CERTIFICATE OF ANALYSIS



Dales Pharmaceuticals

PRODUCT: Urilin 100ml (UK/IRE) ✓

BATCH NO: 84870 ✓

DATE OF MANUFACTURE: August 2016

DATE OF EXPIRY: July 2019 ✓

DATE OF TESTING: September 2016

At the time of testing the results below were obtained for the above product.

<u>Test</u>	<u>Specification</u>	<u>Result</u>
Appearance	Clear, colourless viscous liquid	Complies
Identification		
a. Phenylpropanolamine	Present	Complies
b. Sodium Methylhydroxybenzolate	Present	Complies
c. Sodium Propylhydroxybenzolate	Present	Complies
d. Chlorides	Present	Complies
PH	4.7 – 5.4	4.9
Specific Gravity	1.24-1.37	1.304
Assay Phenylpropanolamine	47.5 – 52.5 mg/ml	50.2mg/ml
Assay SMHB	0.1350 – 0.1650 %w/v	0.1540%
Assay SPHB	0.01350 – 0.01650 %w/v	0.01508%
Microbial Purity	TVC (Bacteria) ≤ 200cfu/g TFC (Fungi) ≤ 20cfu/g E. coli absent in 1g	Complies Complies Absent

Signed: 
R D Burton BSc CBiol MRSB
Qualified Person

Date: 



INVESTOR IN PEOPLE



Dales Pharmaceuticals

CERTIFICATE OF CONFORMITY

Manufacturing Company: Dales Pharmaceuticals
Address: Snaygill Industrial Estate, Skipton, North Yorkshire, BD23 2RW

Manufactured For: Dechra Veterinary Products Ltd.
Address: Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
UK

Product Name: Urilin 100ml UK/IRE ✓

Packed Product Code: 90765

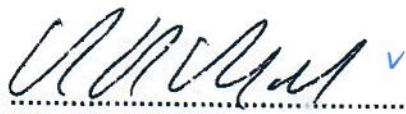
Lot Number: 84870 ✓ Packaging Date: September 2016

Batch Record Review

The documentation for the above mentioned product has been reviewed by a Qualified Person and it has been determined that this lot was manufactured and packaged in accordance with master production documents.

The Product has been manufactured in accordance with the current GMP requirements and approved Marketing Authorisation and complies with the approved specifications.

All details relating to any Process Amendments and Material Reviews are attached. ✓

Signature:  ✓
R D Burton BSc CBiol MRSB
Qualified Person

Date: 09 SEP 16



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23-09-2016 MKO