

CERTIFICATE OF ANALYSIS



PRODUCT: Forthyron Flavoured 400mcg Tablets 250's (AT/HU/EL)

BATCH NO: 76524

DATE OF MANUFACTURE: December 2015

DATE OF TESTING: January 2016

EXPIRY DATE: November 2017

Dales Pharmaceuticals

At the time of testing the results below were obtained for the above product and this batch is released into the market.

No.	Test	Specification	Result
1	Appearance	Off White round tablet with brown spots, quadrisect with side scores, diameter 9mm	Complies
2	Identification Levothyroxine HPLC	Levothyroxine Present HPLC	Complies
	Identification Levothyroxine Colour reaction	Levothyroxine Present Colour reaction	Complies
3	Assay of Levothyroxine Sodium	380 - 420µg/tablet (Release) 360 - 420µg/tablet (Shelf Life)	393µg/tablet
4a	Average Mass	290-310mg	305mg
4b	Weight Deviation	Maximum Minimum	311mg/tablet 300mg/tablet
4c	Weight Uniformity	+/- 5% in at least 18 of 20 tablets (FIO) None outside +/- 10%	Complies
5	Friability	≤1%	0.5%
6	Resistance to Crushing (Scored side up, breakmarks diagonal to crushing plates)	40-100N (Release) Minimum 20N (Shelf Life)	79N
7	Disintegration	NMT 15 minutes	2 minutes
8	Uniformity of Dosage Units	Complies if L1 value of 15.0 is met for 10 tablets (L2 is 25.0 for 30 tablets) <i>Ph Eur 2.9.40</i>	Complies
9	Dissolution Rate*	Q = 70% at 45 minutes (Ph Eur 2.9.3 and USP <711>)	100%
10	Microbial Purity**	TVC (aerobic) NMT 2000 cfu/g TFC (yeasts & moulds) NMT 200 cfu/g <i>E.coli</i> Absent in 1g	N/A N/A N/A

* Test 1 batch per year (or when requested by customer / authorities/stability)
Initially test as described for S₁ below. If S₁ fails to meet acceptance criteria, proceed to S₂. If S₂ fails to meet criteria, proceed to S₃.
S₁ – Test 6 tablets, each unit must be NLT Q + 5%
S₂ – Test a further 6 tablets, the average of 12 units (S₁ + S₂) should be NLT Q. No unit should be less than Q – 15%
S₃ – Test a further 12 tablets, the average of 24 units (S₁ + S₂ + S₃) should be NLT Q. Not more than 2 units should be less than Q – 15% and no unit should be less than Q – 25%

** Test 1 batch per year (or when requested by customer / authorities/stability)

Signed.....

Date.....

R D Burton BSc CBiol MRSB
Qualified Person



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Dales Pharmaceuticals, A trading business of Dechra Ltd. Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW
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Registered Office: Snaygill Industrial Estate, Keighley Road, Skipton, North Yorks. BD23 2RW Registered in England No. 4513124. VAT No. 687 8995 32



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: Dechra Pharmaceuticals Manufacturing Bladel
Handelsweg 25
Bladel, 5531, AE
Netherlands

Product Name: Forthyron Flavoured 400mcg Tablets 250's (AT/HU/EL)


Packed Product Code: 91528

Lot Number: 76524 Packaging Date: January 2016

It is hereby certified that the above information is authentic and accurate.

This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. The batch is released into the market.

Signature: 
R D Burton BSc CBIol MRSB
Qualified Person

Date: 22 JAN 16



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