CERTIFICATE OF ANALYSIS

Dales Pharmaceuticals

PRODUCT: Forthyron Flavoured 200mcg Tablets 250's (AT/HU/EL)
BATCH NO: 88974
DATE OF MANUFACTURE: October 2016
DATE OF TESTING: January 2017
EXPIRY DATE: September 2018

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 7mm		Complies
2	Identification Levothyroxine HPLC	Levothyroxine Present HPLC		Complies
	Identification Levothyroxine Colour reaction	Levothyroxine Present Colour reaction		Complies
3	Assay of Levothyroxine Sodium	190 - 210µg/tablet (Release) 180 - 210µg/tablet (Shelf Life)		198µg/tablet
4a	Average Mass	145 -155mg		151mg
4b	Weight Deviation	Maximum Minimum		153mg/tablet 147mg/tablet
4c	Weight Uniformity	+/- 7.5% in at least 18 of 20 tablets (FIO) None outside +/- 15%		Complies
5	Friability	≤1%		0.5%
6	Resistance to Crushing (Scored side up, breakmarks diagonal to crushing plates)	30-65N (Release) Minimum 15N (Shelf Life)		49N
7	Disintegration	NMT 15 minutes		1 minute
8	Uniformity of Dosage Units	Complies if L1 value of 15.0 is met for 10 tablets (L2 is 25.0 for 30 tablets) *Ph Eur 2.9.40*		Complies
9	Dissolution Rate*	Q = 70% at 45 minutes (Ph Eur 2.9.3 and USP <711>)		N/A
10	Microbial Purity**	TVC (aerobic) TFC (yeasts & moulds) *E.coli*	NMT 2000 cfu/g NMT 200 cfu/g 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 S_1 below. If S_1 fails to meet acceptance criteria, proceed to S_2. If S_2 fails to meet criteria, proceed to S_3.
S_1 – Test 6 tablets, each unit must be NLT Q + 5%
S_2 – Test a further 6 tablets, the average of 12 units (S_1 + S_2) should be NLT Q. No unit should be less than Q – 15%
S_3 – Test a further 12 tablets, the average of 24 units (S_1 + S_2 + S_3) 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 13 JAN 17
R D Burton BSc CBiol MRSB
Qualified Person

INVESTOR IN PEOPLE

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 200mcg Tablets 250's (AT/HU/EL) ✓

Packed Product Code: 91527 ✓

Lot Number: 88974 ✓ Packaging Date: December 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: ..... ✓ Date: 13 JAN 17

R D Burton BSc CBiol MRSB
Qualified Person

INVESTOR IN PEOPLE

12-01-2017 DER