

CERTIFICATE OF ANALYSIS



Dales Pharmaceuticals

PRODUCT: Forthyron Flavoured 200mcg Tablets 250's (AT/HU/EL) ✓
BATCH NO: 70544 ✓
DATE OF MANUFACTURE: September 2015
DATE OF TESTING: September 2015
EXPIRY DATE: August 2017 ✓

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) | 198 µg/tablet |
| 4a | Average Mass | 145 -155mg | 152 mg |
| 4b | Weight Deviation | Maximum Minimum | 154 mg/tablet 150 mg/tablet |
| 4c | Weight Uniformity | +/- 7.5% in at least 18 of 20 tablets (FIO) None outside +/- 15% | Complies |
| 5 | Friability | ≤1% | 0.33% |
| 6 | Resistance to Crushing (Scored side up, breakmarks diagonal to crushing plates) | 30-65N (Release) Minimum 15N (Shelf Life) | 48 N |
| 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) <i>Ph Eur 2.9.40</i> | Complies |
| 9 | Dissolution Rate* | Q = 70% at 45 minutes (Ph Eur 2.9.3 and USP <711>) | 101% |
| 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.....
 K Fraser BSc DPhil CChem MRSC
 Qualified Person
 2nd version (expiry date amended)

Date..... 1 OCT 2015



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

06-10-2015 MKO



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: 70544 ✓ Packaging Date: September 2015

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:  ✓
K Fraser BSc DPhil CChem MRSC
Qualified Person

Date: 28 SEP 2015



INVESTOR IN PEOPLE

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