

CERTIFICATE OF ANALYSIS



Dales Pharmaceuticals

PRODUCT: Forthyron Flavoured 400mcg Tablets 250's (AT/HU/EI)
BATCH NO: 67440
DATE OF MANUFACTURE: June 2015
DATE OF TESTING: July 2015
EXPIRY DATE: May 2017

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

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)	387 µg/tablet
4a	Average Mass	290-310mg	307 mg
4b	Weight Deviation	Maximum Minimum	309 mg/tablet 303 mg/tablet
4c	Weight Uniformity	+/- 5% in at least 18 of 20 tablets (FIO) None outside +/- 10%	Complies
5	Friability	≤1%	0.6%
6	Resistance to Crushing (Scored side up, breakmarks diagonal to crushing plates)	40-100N (Release) Minimum 20N (Shelf Life)	82 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>)	104%
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.....
R D Burton BSc CBIOL MSB
Qualified Person

Date..... 17 Jul 15



INVESTOR IN PEOPLE