

**CERTIFICATE OF ANALYSIS**

PRODUCT: Forthyron Flavoured 200mcg Tablets 250's
AT/HU/EL
STOCK CODE: 91527

BATCH NO: 107587

MARKETING AUTH N^o: AT: Z.Nr 8-01013
HU: 3056/2/11 MgSzH ÁTI
EL: 42035/11-6-2012

DATE OF MANUFACTURE: April 2018
DATE OF TESTING: May 2018

EXPIRY DATE: March 2020

Manufacturing and test site: Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road,
Skipton, North Yorkshire, United Kingdom, BD23 2RW

Analytical Report Ref: 570(9)

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)	199.1µg/tablet
4a Average Mass	145 -155mg	152mg
4b Weight Deviation	Maximum Minimum	154.76mg/tablet 149.07mg/tablet
4c Weight Uniformity	+/- 7.5% in at least 18 of 20 tablets (FIO) None outside +/- 15%	Complies
5 Friability	≤1%	0.4%
6 Resistance to Crushing (Scored side up, breakmarks diagonal to crushing plates)	30-65N (Release) Minimum 15N (Shelf Life)	59N
7 Disintegration	NMT 15 minutes	1minutes
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>)	N/A
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



INVESTOR IN PEOPLE

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