

Certificate of analysis

Name of the product: Forthyron Flavoured 200 µg



Animal Health

Product number : 97071208
Batch number Dechra : 933643
Batch number Supplier : 14D14
Manufacturing date : 04-2014
Expiry date : 04-2016

Our ref. number : CB
Packing : 250 tabl
Destination : Hungary
CoA version : SC-LAB97071208.3.0

DETERMINATIONS	SPECIFICATIONS	RESULTS
APPEARANCE OF TABLETS	Off white round tablet with brown spots,quadrisect with side scores, diameter 7 mm	Off white round tablet with brown spots,quadrisect with side scores, diameter 7 mm
APPEARANCE PRIMARY PACKAGING	No deviations	No deviations
IDENTIFICATION OF LEVOTHYROXINE	Positive	Positive
ASSAY OF LEVOTHYROXINE SODIUM (µg/tablet)	190 – 210	191
AVERAGE MASS (mg/tablet)	145 – 155	150
FRIABILITY (%)	Max. 1	0
RESISTANCE TO CRUSHING (N)	30 – 65	57
UNIFORMITY OF DOSAGE UNITS	Complies to Ph. Eur 2.9.40	Complies
MICROBIOLOGICAL QUALITY	Complies to Ph. Eur 5.1.4 (Non-aqueous preparations for oral use)	* not applied
DISINTEGRATION	Max. 15 min.	1
DISSOLUTION RATE	Q=70 after 45 min. (Ph.Eur.2.9.3)	* not applied

* Not routinely tested, at least once a year

Conclusion : Conform specifications.

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with Good Manufacturing Practices

Els de Meijer

12 AUG 2014

Qualified Person

Dechra

