



Certificate of Analysis

3.88839.0050 THYROZOL 10 - (50) CHL

Batch G00PP8

Parameter	Release-Specification	Results
Appearance	grey-orange round, biconvex film-coated tablet, with dividing score on both sides thickness approx. 3.7 mm, diameter approx. 9.1 mm	conforms
Mass		
Mean mass	248 - 263 mg	254.6 mg
Uniformity of mass	must conform to Ph. Eur.*	250.2 - 258.2 mg RSD = 0.85 %
Dimensions		
Diameter	approx. 9.1 mm	9.1 - 9.1 mm
Thickness	approx. 3.7 mm	3.5 - 3.6 mm
Hardness (acc. to Ph. Eur.*)	40 - 140 N	82 - 104 N mean value: 91 N
Water content (Karl Fischer method acc. to Ph. Eur.*)	max. 5 %	4.7 %
Identity by HPLC by NIR	Thiamazole positive positive	Thiamazole positive positive
Assay by HPLC	95 - 105 % of the declared content Thiamazole	99.99 % of the declared content Thiamazole
Chemical purity by HPLC		
each degradation product	max. 0.2 %	conforms <=0.2%
sum of degradation products	max. 0.5 %	0.00 %
Dissolution (paddle apparatus)	min. 80 % in 15 min (Q = 75 %) (acceptance criteria acc. to Ph.Eur.*)	95.6 - 98.5 % mean value: 96.9 % in 15 min Stage 1 fulfilled

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Microbial	must conform	not tested
purity	to Ph. Eur. 5.1.4*	
(random		
testing)		

* current version at time of investigation

Manufacturing date:	25.06.2020
Expiry date:	31.05.2024

Hereby I certify that this lot has been tested in accordance with the marketing authorisation and the european guide to good manufacturing practice for medicinal products.

Dr. Tagliazucca

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