

Certificate of Analysis

Product name: Thyreoidum
Batch number / Weight: 21I02-B01-215329 / 100 G
Analysed according to: USP

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------------|--|---------|----------|-----------------|
| Appearance | Yellowish to buff colored amorphous powder | Conform | | |
| Identification | Conform | Conform | | |
| Loss on drying | $\leq 6,0$ | 2,0 | % | |
| Inorganic iodides | $\leq 0,01$ | Conform | % | |
| Assay Levothyroxine (T4) | 90,0-110,0 | 103,0 | % | |
| Assay Liothyronine (T3) | 90,0-110,0 | 97,9 | % | |
| Total aerobic microbial count (TA) | $\leq 10^3$ CFU/g | <10 | CFU / g | |
| Total yeasts and moulds (TYMC) | $\leq 10^2$ CFU/g | <10 | CFU / g | |
| E. coli | Negative | Conform | /gram | |
| Salmonella | Negative | Conform | /10 gram | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

25-02-2022

Expiration: 31-07-2023

Conclusion: APPROVED

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