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Company data are stored at the Register of Legal Entities of the Republic of Lithuania

# CERTIFICATE OF ANALYSIS

## TheraPure™ GMP, N¹-Methylpseudo-UTP, 100 mM Solution

| | |
|---|---|
| **Catalog number:** | **R0491SKB012** |
| **Sample Catalog number:** | **R0491SKSMP3** |
| **Lot number:** | **CC-XXXXXXX** |
| **Manufacturing Date:** | **YYYY-MM-DD** |
| **Expiry Date:** | **YYYY-MM-DD** |
| **CoA Issue No.:** | **XXXX** |

| | |
|---|---|
| Quantity: | 100 mL / 250 µL |
| Storage: | at -20±5°C |
| Composition: | TheraPure™ GMP, N¹-Methylpseudo-UTP is a high purity methylated uridine 5'-triphosphate supplied as 100 mM aqueous solution adjusted to pH 7.5-7.9 with NaOH. |



### Compliance statement

This product has been manufactured, tested, and released in compliance with applicable regulations and current quality standards, as well as locally imposed requirements as per written agreements.

This product has been manufactured, packed, and tested in compliance with the defined manufacturing processes.

The relevant records for this lot have been reviewed for accuracy, completeness, and compliance with established standard operating procedures. Completeness includes confirmation that all quality events associated with the lot have been closed and accepted by QA of Manufacturer.

### Regulatory statement

For research use or further manufacturing. Not for diagnostic use or direct administration into humans or animals.

## QUALITY CONTROL

| Parameter | Method | Requirement | Result |
|---|---|---|---|
| Color | Ph. Eur. 2.2.2., method I; USP <630> | Colorless solution | Conforms |
| Clarity | Ph. Eur. 2.2.1. | Clear (≤ 3 NTU) | Conforms |
| Concentration | Spectrophotometry under UV at 271 nm (pH 7.0), in-house method | 100 ± 3 mM | 000 mM |
| pH | Potentiometric determination of pH, Ph. Eur. 2.2.3.; USP <791> | 7.5 – 7.9 | 0.0 |
| Identity | RP-HPLC, in-house method | Conforms to reference standard | Conforms |
| Purity | RP-HPLC, in-house method | ≥ 99% triphosphate | 00% |
| Endo – and Exonucleases | Fluorimetric assay, in-house method | Not detectable (<LOQ, 0.67 pg/µl) | Conforms |

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| Parameter | Method | Requirement | Result |
|---|---|---|---|
| Ribonucleases | Incubation of RNA transcript with $N^1$-MepUTP, in-house method | Not detectable | Conforms |
| Endodeoxyribonucleases | Incubation of supercoiled pUC19 plasmid DNA with $N^1$-MepUTP, in-house method | Not detectable | Conforms |
| $\lambda_{max}$ | Spectrophotometric measurements at pH 7.0, in-house method | 271 ± 2 nm | 000 nm |
| Bacterial endotoxins | Gel-clot method: Method A., Ph. Eur. 2.6.14.; USP <85> | < 1 EU/mL | Conforms |
| Microbial contamination | Microbial enumeration test: Membrane Filtration method, Ph. Eur. 2.6.12.; USP <61> | TAMC: < 3.0 CFU/mL<br>TYMC: < 2.0 CFU/mL | Conforms |



ISO CERTIFICATION
Manufactured by Thermo Fisher Scientific Baltics UAB, in compliance with ISO 9001 and ISO 13485 certified quality management system.

**CoA is issued by**

Quality Assurance Department Date

**CoA is verified and approved by**

Quality Assurance Department Date