Quality documentation package for TheraPure GMP products

Providing the information to navigate quality challenges

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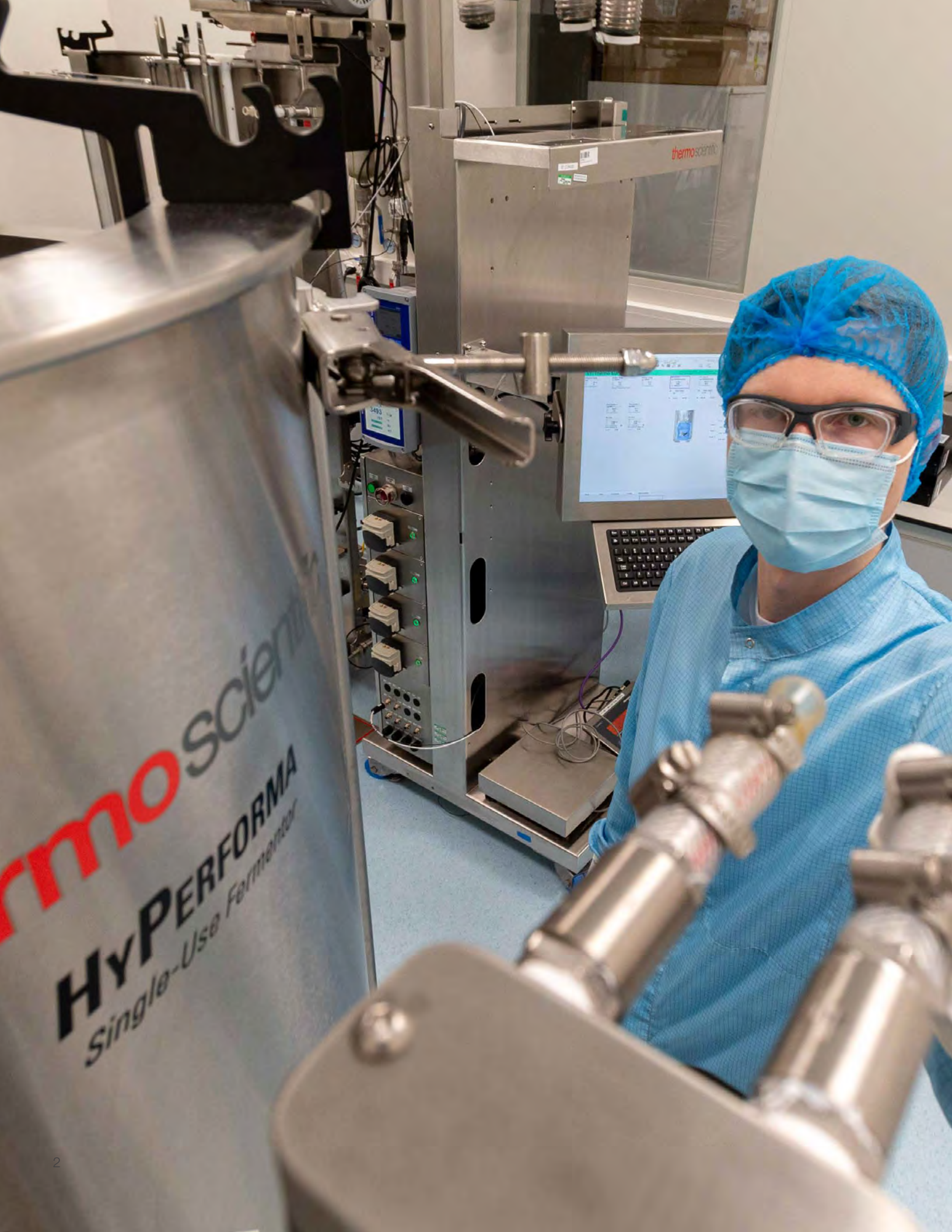

HyPerforma
Single-Use Fermentor

Accelerate your drug development efforts with easy access to key product quality information

Thermo Scientific™ TheraPure™ GMP* products are manufactured in accordance with relevant good manufacturing practice (GMP) principles as outlined in ICH Q7 or equivalent guidance documents or standards, and they are analyzed following ICH Q2 guidelines. This helps ensure these products are manufactured to exceptionally stringent product quality and manufacturing process control standards.

The TheraPure GMP quality documentation package makes product quality information easily accessible to help:

- Facilitate risk assessment and risk management
- Simplify material qualification
- Streamline process development

* "TheraPure GMP" refers to the quality level of the raw, ancillary, or starting materials to be used for further manufacturing. TheraPure GMP products are manufactured in facilities with ISO 9001–certified quality management systems operating in accordance with relevant good manufacturing practice (GMP) principles as outlined in ICH Q7 or equivalent guidance documents or standards.

Answers to help you manage risks

The documentation package available with each TheraPure GMP nucleotide or enzyme product includes:

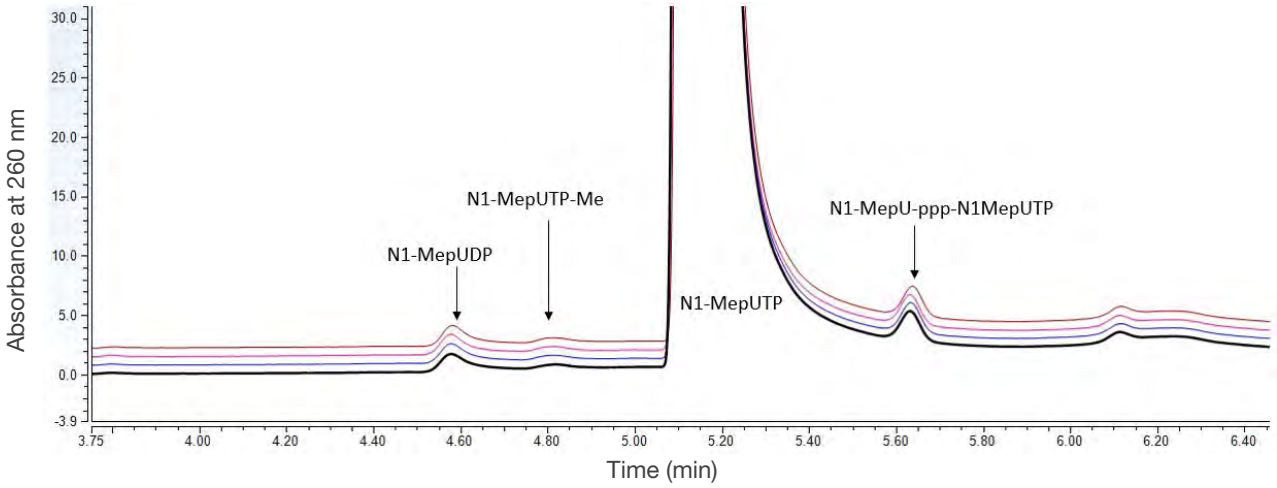
- Certificate of analysis (CoA)
- Certificate of origin (CoO)
- TSE/BSE statement
- Nitrosamine statement
- Melamine statement
- Compendial test results (bioburden, endotoxin, residual host cell materials, etc.)
- Impurity profile
- Stability test results
- Drug master file


CERTIFICATE OF ANALYSIS

T7 RNA Polymerase, AOF

QUALITY CONTROL

A major benefit of using TheraPure GMP products is that they are made and tested by validated processes and assays. This helps ensure their consistency and minimizes batch-to-batch variability.



Consistent Thermo Scientific™ TheraPure™ GMP N1-Me-pUTP product made by a validated process. This figure shows an overlay of the HPLC analysis of four lots of TheraPure GMP N1-Me-pUTP. Each lot of material is very consistent in terms of the type and level of impurity present in the TheraPure GMP product.

Get more information at **thermofisher.com/therapure**

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