

Data Sheet

GMP Recombinant Human Thrombopoietin (rh TPO)

Order No.: 1017-050, 1017-1000

Product Characteristics

Source E. coli

Description Truncated human TPO, accession # P40225, Ser22-Leu195

Formulation N-terminal Met and 6xHis-tag

Quality Parameters

Identity Confirmed by DNA-sequencing of the expression plasmid in end-of-production

cells and N-terminal sequencing of the final product

Activity 10 - 40 x 10⁶ U/mg calibrated against against an in-house reference standard

Measured in a cell proliferation assay using a TPO-dependent cell line, MO7e

Purity ≥ 98 %, as determined by SDS-PAGE (under reducing and non-reducing

conditions, visualized by Coomassie staining)

Product-related

proteins

≤ 10 % oligomers as determined by SDS-PAGE (under non-reducing conditions,

visualized by Coomassie staining)

≤ 2 % fragments, as determined by SDS-PAGE (under reducing conditions,

visualized by Coomassie staining)

Host-cell DNA \leq 200 ng/mg, as determined with a fluorimetric assay

Host-cell protein $\leq 1.0 \,\mu g/mg$, as determined by ELISA

Endotoxin ≤ 50 EU/mg, as determined by LAL gel clot test according to Ph. Eur. and USP

Sterility Sterility test according to Ph. Eur. and USP of the vialed product (direct

inoculation)

Mass per vial 1017-050: 43 - 57 μg, as determined by BCA assay

1017-1000: 900 – 1100 μg, as determined by spectrophotometrical

measurement

本品は研究用試薬です。治療および診断目的にはご使用できません。



Shipment & Storage

Transport Ambient temperature. Please refer to Technote (www.cellgenix.com)

Expiry Minimum 6 months from date of shipping

Storage & Stabilty Store lyophilized cytokine at -20°C or below.

Store a 250 µg/ml cytokine solution

• 4 weeks at 2°C to 8°C under sterile conditions after reconstitution. Store in the original container.

• 4 months at -20°C or below under sterile conditions after reconstitution. Store in 60 μl aliquots in polypropylene cryogenic vials.

Avoid repeated freeze/thaw cycles.

Handling Instructions

Reconstitution Recommended in sterile water to a final concentration of 250 μg/ml for 50 μg

vials or 500 μ g/ml for 1000 μ g vials.

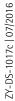
Dilution Recommended in CellGro® / CellGenix™ serum-free media. For dilution with

protein free medium, a carrier protein (0.1-1% albumin or 1-10% appropriate serum) has to be included. Failure to dilute product according to these

instructions may result in loss of activity.

Quality Statement

This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. No animal-or human-derived materials were used during the manufacturing. USP chapter <1043> "ancillary materials for cell, gene, and tissue-engineered products" has been considered in the design of this product.



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