

Data Sheet

GMP Recombinant Human Interleukin-7 (rh IL-7)

Order No.: 1010-050

Product Characteristics

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| Source | <i>E. coli</i> |
| Description | Human Interleukin-7, accession # P13232, Asp26-His177 N-terminal Met and C-terminal 6xHis-tag Molecular mass 18.3 kDa |
| Formulation | Lyophilized from 200 µl of a 0.2 µm-filtered solution containing 25 mM sodium phosphate, 150 mM sodium chloride and 0.1 % polysorbate 20, pH 7.5 |

Quality Parameters

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| Identity | Confirmed by DNA-sequencing of the expression plasmid in end-of-production cells and N-terminal sequencing of the final product |
| Activity | 50 – 200 x 10 ⁶ IU/mg calibrated against NIBSC #90/530 Measured in a cell proliferation assay using an IL-7-dependent cell line, IxN/2b |
| Purity | ≥ 97 %, 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 reducing conditions, visualized by Coomassie staining) |
| Host-cell DNA | ≤ 200 ng/mg, as determined with a fluorimetric assay |
| Host-cell protein | ≤ 1.0 µg/mg, as determined by ELISA |
| Endotoxin | ≤ 25 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 vial product (direct inoculation) |
| Mass per vial | 1010-050: 43 – 57 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

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| Transport | Ambient temperature. Please refer to Technote (www.cellgenix.com) |
| Expiry | Minimum 6 months from date of shipping |
| Storage & Stability | Store lyophilized cytokine at -20°C or below. Store a 250 µg/ml cytokine solution <ul style="list-style-type: none">• 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

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| Reconstitution | Recommended in sterile water to a final concentration of 250 µg/ml. |
| 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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