

Data Sheet

GMP Recombinant Human Activin A (rh Activin A)

Order No.: 1022-050

Product Characteristics

Source	<i>E. coli</i>
Description	Human Activin A (also known as inhibin beta A chain), accession # P08476, Gly311-Ser426 N-terminal Met Molecular mass 26.2 kDa per homodimer
Formulation	Lyophilized from 200 µl of a 0.2 µm-filtered solution containing 20 mM glycine, 150 mM sodium chloride and 3 % mannitol, pH 9.5

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	0.6 – 2.5 x 10 ³ IU/mg calibrated against NIBSC #91/626 Measured by inhibition of proliferation MPC-11 cells
Purity	≥ 97 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	≤ 5 % oligomers, as determined by SDS-PAGE (under non-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	≤ 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 vial product (direct inoculation)
Mass per vial	43 – 57 µg as determined by spectrophotometrical measurement

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Shipment & Storage

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. Avoid repeated freeze/thaw cycles.

Handling Instructions

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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