

Data Sheet: CellGro® / CellGenix™**GMP Recombinant Human Platelet Derived Growth Factor-BB****(rh PDGF-BB)****Order No.: 1009-050**

Source	A DNA sequence encoding the mature PDGF-BB protein was expressed in <i>E. coli</i>
Molecular mass	The methionyl form of the <i>E. coli</i> expressed mature human PDGF-BB contains 110 amino acid residues and has a molecular mass of 12 kDa (monomer)
Structure	Disulfide linked homodimer (PDGF-BB)
Identity	Confirmed by DNA-sequencing of the expression plasmid in end of production (EOP)-cells, and N-terminal sequencing of the final product
Purity	≥ 97%, as determined by SDS-PAGE (visualized by Coomassie staining under reducing conditions) and SE-HPLC
Endotoxin level	< 1000 EU/mg, as determined by LAL gel clot test according to Ph.Eur.; typically < 100 EU/mg
Residual host-cell DNA	≤ 200 ng/mg, as determined by a fluorimetric assay
Activity	1x10 ⁶ – 10x10 ⁶ IU/mg calibrated with the 1 st International standard NIBSC, #94/728 Measured in a cell proliferation assay using a human factor-dependent cell line, Balb/3T3 (Raines, E.W. et al. [1985] Methods Enzymol. 109: 749)
Sterility	Sterility test according to Ph.Eur. of the vial product (direct inoculation)
Formulation	Lyophilized from a 250 µm/ml, 0.2µm sterile-filtered solution in PBS without any carrier materials and preservatives
Amount per vial	50 ± 7.5 µg, as determined by spectrophotometrical measurement at 280 nm using PBS as reference (A ₂₈₀ = 0.48 for a concentration of 1 mg/ml PDGF-BB in PBS)
Transport	Ambient temperature
Storage at	-20°C or below. Avoid repeated freeze-thaw cycles
Shelf life	Minimum 6 months from date of shipping
Intended use	For clinical ex vivo use. Not intended for human in vivo application
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 manufacturing. USP chapter <1043> “ancillary materials for cell, gene, and tissue-engineered products” has been considered in the design of this product.

Manufacturer

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