

Title (en)

METHOD FOR PRODUCTION OF A THERAPEUTICALLY PURE GRANULOCYTE MACROPHAGE - COLONY STIMULATING FACTOR

Title (de)

VERFAHREN ZUR HERSTELLUNG EINES THERAPEUTISCH REINEN GRANULOZYTENMACROPHAGEN-KOLONIESTIMULIERENDEN FAKTORS

Title (fr)

PROCEDE POUR LA PRODUCTION D'UN FACTEUR STIMULANT LES COLONIES DE GRANULOCYTES-MACROPHAGES

Publication

EP 1833846 A2 20070919 (EN)

Application

EP 05732861 A 20050318

Priority

- IN 2005000088 W 20050318
- IN 1343CH2004 A 20041209

Abstract (en)

[origin: WO2006061851A2] A simple and scaleable process is provided for obtaining recombinant human GM-CSF expressed in microbial cells, secreting mature GM-CSF, culturing these cells and purifying the protein in good yield and of a therapeutic grade quality. The steps include cloning, fermentation and purification of the protein. The purified protein is got by a process that involves lysing the microorganism, extraction of the processed and unprocessed forms of GM-CSF from the membrane pellet and selectively purifying the processed form of the protein from the unprocessed form by a two-step chromatography procedure. The purity of the processed form of GM-CSF (without signal peptide) obtained has endotoxin units, host cell proteins and host cell DNA within the specified compendial limits for therapeutic proteins.

IPC 8 full level

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