



Certificate of Origin

Date 12-August-2010

Product Name Cell Therapy Systems Recombinant Human GM-CSF

Catalog Number CTP2011, CTP2013

Lot Number Information applies to all lots produced.


Manufacturing Information Manufactured under ISO13485 Quality Standard

Manufacturing Site Invitrogen, Camarillo, California, USA

Raw Material Information Recombinant human GM-CSF is produced in E. coli and purified via sequential chromatography. The product contains no materials directly of animal origin. The product does utilize animal derived components in the manufacturing process.

Animal Derived Components: The fermentation feed contains tryptone derived from bovine milk of US or Australia origin. The fermentation media is sterilized at 122.5°C for 45 minutes, 15 psi. GM-CSF is purified by immobilized metal affinity chromatography (non-animal) and ion exchange chromatography. The leader sequence is cleaved by thrombin derived from human plasma. The serum is certified to be negative for HBsAg and for Antibodies to HIV and HCV. The final purification step is by size exclusion chromatography.

This document was prepared by:



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