The leading global supplier of preclinical and cGMP grade CRM197

WWW.CRM197.COM
Pfenex CRM197 is a recombinant form expressed in *Pseudomonas fluorescens* using the Pfenex Expression Technology™ platform.
CRM197 Carrier Protein
Consistency, Scalability, and Compliance

CRM197 is a non-toxic mutant of diphtheria toxin\textsuperscript{1,2} having a single amino acid substitution of glutamic acid for glycine. CRM197 is a well defined protein and functions as a carrier for polysaccharides and haptens making them immunogenic. It is utilized as a carrier protein in a number of approved conjugate vaccines for diseases such as meningitis and pneumococcal bacterial infections.

Pfenex CRM197 is a recombinant form expressed in \textit{Pseudomonas fluorescens} using the Pfenex Expression Technology™ platform. Pfenex CRM197 is identical in both structure and function to the mutant protein produced in \textit{Corynebacterium diphtheriae}. The protein is available in pre-clinical and cGMP grades in amounts that will meet any clinical or commercial requirement.

\textbf{DESCRIPTION}

\textbf{Source:}
\textit{Pseudomonas fluorescens} expressed recombinant CRM197

\textbf{Product Molecular Mass:}
58.4 kDa

\textbf{SPECIFICATIONS}

\textbf{Purity:}
> 95% CRM197 by SDS-PAGE
A and B chain content
< 5% of total CRM197

\textbf{Endotoxin:}
< 100 EU/mg of protein by LAL method

\textbf{Dimer:}
< 5%

\textsuperscript{2} Mekada, E., and Uchida, T. J. Biol. Chem. 260: 12148-12153 (1985)
VACCINE DEVELOPMENT JUST GOT A LITTLE EASIER

Highest quality CRM197 commercially available

- Pre-clinical and cGMP grade recombinant CRM197 carrier protein available
- Product and process consistency from pre-clinical grade through cGMP grade
- Speed your vaccine into the clinic
- Avoid slow, complex and costly production in a pathogenic organism
- Biologics Master File access to support regulatory filings and the equivalent for ex-US filings
- Cost-effective solution for sourcing critical material for vaccine development and commercialization

10-valent pneumococcal conjugate vaccine using Pfenex CRM197 as carrier
OPA (opsonophagocytosis assay) has been shown to be the best functional correlate of protection.

PFENEX CRM197

Conjugation with Polysaccharides

Pfenex CRM197 is identical to native CRM197.
The conjugation efficiency of Pfenex CRM197 is equivalent to native CRM197.

Vaccine candidates using Pfenex CRM197 are currently being evaluated in the US, Europe, and Asia in pre-clinical through Phase 3 trials.

Control CRM197 was produced in *Corynebacterium diphtheriae*. 

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\(^3\) The Recombinant CRM197 (bulk) Product has been manufactured as per the Current Good Manufacturing Practices regulations and guidances ICH Q7 and ICH Q11, as appropriate, for Recombinant CRM197 (bulk) as an Active Substance Starting Material intended for further manufacturing of suitable drug substance and/or drug product by end user.
Q: Where does Pfenex manufacture CRM197?
A: Pfenex CRM197 is manufactured under cGMP at Serum Institute of India (SII), a world-class manufacturer of vaccines.

Q: What documentation will I receive with my CRM197 shipment?
A: A Certificate of Analysis is provided for reagent grade orders and for cGMP orders a Certificate of Analysis and a Certificate of Origin (stating that no animal-derived components were used in the manufacture of the product), and recommended storage conditions.

Q: What supporting regulatory documentation will Pfenex provide for regulatory filings?
A: For regulatory filings in the USA, Pfenex will provide a Letter of Authorization to allow the FDA to reference BMF for CRM197. For regulatory filings other than the US FDA, Pfenex will provide a comprehensive data package similar to BMF in support of the clients filing.

97.4% sequence coverage and are homologous