§ 113.111 Clostridium Perfringens Type C Toxoid and Bacterin-Toxoid.

Clostridium Perfringens Type C Toxoid and Clostridium Perfringens Type C Bacterin-Toxoid shall be produced from a culture of Clostridium perfringens Type C which has been inactivated and is nontoxic. Each serial shall meet the applicable requirements in § 113.100 and shall be tested for purity, safety, and potency as prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Purity test. Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in §113.26.

(b) Safety test. Bulk or final container samples of completed product from each serial shall be tested for safety as provided in §113.33(b).

(c) Potency test. Bulk or final container samples of completed product from each serial shall be tested for potency using the Beta toxin-neutralization test provided in this paragraph.