§ 113.114 Tetanus Toxoid

Tetanus Toxoid shall be produced from a culture of Clostridium tetani which has been inactivated and is nontoxic. The toxoid may be either absorbed, precipitated, or purified and concentrated. Each serial of biological product containing tetanus toxoid fraction shall meet the applicable requirements in §113.100 and shall be tested for purity, safety, and potency as prescribed in this section. A serial or subspecies found unsatisfactory by any prescribed test shall not be released.

(a) Purity test. Final container samples of completed product from each serial and subspecies 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. A group of 10 guinea pigs consisting of an equal number of males and females weighing 450 to 550 grams shall each be injected subcutaneously with 0.4 of the largest dose recommended on the product labels.

(1) Six weeks after injection, all surviving guinea pigs shall be bled and equal portions of serum, but not less than 0.5 ml from each, shall be pooled. For a valid test, the pool shall contain the serum from at least eight animals.

(2) The antitoxin titer of the pooled serum shall be determined in antitoxin units (A.U.) per ml using an enzyme-linked immunosorbent assay method acceptable to the Animal and Plant Health Inspection Service.

(3) If the antitoxin titer of the serum pool is at least 2.0 A.U. per ml, the serial is satisfactory. If the antitoxin titer of the serum pool is less than 2.0 A.U. per ml, the serial may be retested by the following procedure: Provided, That, if the serial is not retested, it shall be declared unsatisfactory.

(4) For serials in which the serum pool contains less than 2.0 A.U. per ml, the individual serum that constituted the pool may be tested by the enzyme-linked immunosorbent assay. If at least 80 percent of the individual serums have an antitoxin titer of at least 2.0 A.U. per ml, the serial is satisfactory. If less than 80 percent of the individual serums have an antitoxin titer of at least 2.0 A.U. per ml, the serial is unsatisfactory and shall not be retested further.