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§ 113.105 Leptospira Hardjo Bacterin.

Leptospira Hardjo Bacterin shall be produced from a culture of *Leptospira hardjo* which has been inactivated and is nontoxic. Each serial of biological product containing *Leptospira hardjo* 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 found unsatisfactory by any 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 § 113.38.

(c) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency using the test written into the filed Outline of Production.

[40 FR 17003, Apr. 16, 1975, as amended at 40 FR 20067, May 8, 1975. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66785, Dec. 26, 1991]

§ 113.106 Clostridium Chauvoei Bacterin.

Clostridium Chauvoei Bacterin shall be produced from a culture of *Clostridium chauvoei* which has been inactivated and is nontoxic. Each serial of biological product containing *Clostridium chauvoei* fraction shall meet the applicable requirements in § 113.100 and shall be tested for purity, safety, and potency as prescribed in this section. Serials found unsatisfactory by any 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 § 113.38.

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

(1) Each of at least 8 but not more than 10 guinea pigs, each weighing 300 to 500 grams, shall be injected subcutaneously with a guinea pig dose. A second guinea pig dose shall be injected 21 to 23 days after the first dose. Each guinea pig dose shall be one-fifth of the dose recommended on the label for a calf.

(2) *Clostridium chauvoei* challenge material, available upon request from Animal and Plant Health Inspection Service, shall be used for challenge 14 to 15 days following the last injection of the product. Each of eight vaccinates and each of five additional nonvaccinated guinea pigs for controls shall be injected intramuscularly with approximately 100 LD_{50} of challenge material. This dose shall be determined by statistical analysis of results of titrations of the challenge material. The vaccinates and controls shall be observed for 3 days postchallenge and all deaths recorded.

(3) For a valid test, at least 80 percent of the controls shall die within the 3 day post-challenge observation period. If this requirement is met, the results of the potency test shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths for an unsatisfactory test
1	8	8	1 or less	3 or more.
2	8	16	4 or less	5 or more.

The second stage shall be required only when exactly two animals die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

[39 FR 16862, May 10, 1974, as amended at 45 FR 40100, June 13, 1980. Redesignated at 55 FR 35562, Aug. 31, 1990 and amended at 56 FR 66784, 66785, Dec. 26, 1991]

§ 113.107 Clostridium Haemolyticum Bacterin.

Clostridium Haemolyticum Bacterin shall be produced from a culture of *Clostridium haemolyticum* which has been inactivated and is nontoxic. Each serial of biological product containing *Clostridium haemolyticum* 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 found unsatisfactory by any 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 § 113.38.

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

(1) Each of at least 8 but not more than 10 guinea pigs, each weighing 300 to 500 grams, shall be injected subcutaneously with a guinea pig dose. A second guinea pig dose shall be injected 21 to 23 days after the first dose. Each guinea pig dose shall be one-fifth of the dose recommended on the label for a calf.

(2) *Clostridium haemolyticum* challenge material, available upon request from Animal and Plant Health Inspection Service, shall be used for challenge 14 to 15 days following the last injection of the product. Each of eight vaccinates and each of five additional nonvaccinated guinea pigs for controls shall be injected intramuscularly with approximately 100 LD_{50} of challenge material. This dose shall be determined by statistical analysis of results of titrations of the challenge material. The vaccinates and controls shall be observed for 3 days postchallenge and all deaths recorded.

(3) For a valid test, at least 80 percent of the controls shall die within the 3 day post-challenge observation period. If this requirement is met, the results of the potency test shall be evaluated according to the following table:

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths for an unsatisfactory test
1	8	8	1 or less	3 or more.
2	8	16	4 or less	5 or more.

The second stage shall be required only when exactly two animals die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

[39 FR 16862, May 10, 1974, as amended at 40 FR 20067, May 8, 1975; 45 FR 40100, June 13, 1980. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66784, 66785, Dec. 26, 1991]

§ 113.108 Clostridium Novyi Bacterin-Toxoid.

Clostridium Novyi Bacterin-Toxoid shall be produced from a culture of *Clostridium novyi* which has been inactivated and is nontoxic. Each serial of biological product containing *Clostridium novyi* 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 found unsatisfactory by any 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 § 113.38.

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

(1) When used in this test, the following words and terms shall mean:

(i) *International antitoxin unit.* (I.U.) That quantity of Alpha Antitoxin which reacts with Lo and L+ doses of Standard Toxin according to their definitions.

(ii) *Lo dose.* The largest quantity of toxin which can be mixed with one unit of Standard Antitoxin and not cause sickness or death in injected mice.

(iii) *L+ dose.* The smallest quantity of toxin which can be mixed with one unit of Standard Antitoxin and cause death in at least 80 percent of injected mice.

(iv) *Standard antitoxin.* The Alpha Antitoxin preparation which has been standardized as to antitoxin unitage on the basis of the International *Clostridium novyi* Alpha Antitoxin Standard and which is either supplied by or acceptable to the Animal and Plant