Isolate, Type 4, 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 shall be tested for viable bacteria and fungi as provided in 9 CFR 113.26.

(b) *Safety test.* Observation of the vaccinated turkeys during the prechallenge period of the potency test provided in paragraph (c) of this section shall constitute the safety test. If unfavorable reactions that are attributable to the product occur, the serial is unsatisfactory. If unfavorable reactions that are not attributable to the product occur in one turkey, test results shall be determined by observing the remaining 20 turkeys. The test is inconclusive and may be repeated if unfavorable reactions that are not attributable to the product occur in two or more turkeys, but the serial is unsatisfactory if the test is not repeated.

(c) *Potency test.* Bulk or final container samples of completed product shall be tested for potency of the Type 4 strain, using the two-stage test provided in this paragraph. Turkeys at least 6 weeks old obtained from the same source and hatch shall be properly identified and used as provided in this paragraph.

(1) *Vaccinates.* Each of not more than 21 turkeys shall be vaccinated with the dose and by the route recommended on the label. A second dose shall be given after 3 weeks and the turkeys observed for an additional 2-week prechallenge period.

(2) *Unvaccinated controls.* Each of not more than 11 turkeys shall be held as controls.

(3) *Challenge.* Not less than 14 days after the second dose, each of 20 vaccinates, and each of 10 unvaccinated controls shall be challenged intramuscularly with virulent *Pasteurella multocida,* Strain P–1662, Type 4 (Little and Lyons classification) and observed daily for a 14-day postchallenge period. Only dead birds shall be considered in evaluating the product.

(4) *Validity requirements.* Eight or more unvaccinated controls must die for the test to be valid. If this requirement is met, the potency test results are evaluated according to stage one of the following table. The test is inconclusive and may be repeated if the validity requirement is not met, but the serial is unsatisfactory if the test is not repeated.

Stage	Number of vaccinates	Cumulative number of vaccinates	Cummulative total number of dead vaccinates for_____	
			Satisfactory serial	Unsatisfactory serial
1	20	20	6 or less	9 or more.
2	20	40	15 or less ...	16 or more.

(5) The serial shall pass or fail based on the stage one results of the potency test. However, the second stage may be conducted if seven or eight vaccinates die in stage one, but the serial is unsatisfactory if the second stage is not conducted.

(6) The second stage shall be conducted in a manner identical to the first stage. The serial shall be evaluated according to stage two of the table. On the basis of accumulated results from the data of both stage tests, a serial shall either pass or fail the second stage.

[47 FR 5795, Feb. 4, 1982; 47 FR 6817, Feb. 17, 1982, as amended at 52 FR 9117, Mar. 23, 1987. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66785, Dec. 26, 1991]

§ 113.117 Pasteurella Multocida Bacterin, Avian Isolate, Type 1.

Pasteurella Multocida Bacterin, Avian Isolate, Type 1, shall be prepared from cultures of *Pasteurella multocida,* avian isolate, Type 1 (Little and Lyons classification), which have been inactivated and are nontoxic. Each serial of biological product containing Pasteurella Multocida Bacterin, Avian Isolate, Type 1, 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 shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Observation of the vaccinated chickens during the prechallenged period of the potency

test provided in paragraph (c) of this section shall constitute the safety test. If unfavorable reactions that are attributable to the product occur, the serial is unsatisfactory. If unfavorable reactions that are not attributable to the product occur in one chicken, test results shall be determined by observing the remaining 20 chickens. The test is inconclusive and may be repeated if unfavorable reactions that are not attributable to the product occur in two or more chickens, but the serial is unsatisfactory if the test is not repeated.

(c) *Potency test.* Bulk or final container samples of completed product shall be tested for potency of the Type 1 strain, using the two-stage test provided in this paragraph. Chickens, at least 12 weeks of age, obtained from the same source and hatch, shall be properly identified and used as provided in this paragraph.

(1) *Vaccinates.* Each of not more than 21 chickens shall be injected with the dose and by the route recommended on the label. A second dose shall be injected after 3 weeks and the chickens observed for an additional 2 week prechallenge period.

(2) *Unvaccinated controls.* Each of not more than 11 chickens shall be held as controls.

(3) *Challenge.* Not less than 14 days after the second injection, each of 20 vaccinates, and each of 10 unvaccinated controls shall be challenged intramuscularly with a minimum of 250 colony-forming units of virulent *Pasteurella multocida,* Strain X–73, Type 1 (Little and Lyons classification) and observed daily for a 14-day postchallenge period. Only dead birds shall be considered in evaluating the product.

(4) *Validity requirements.* Eight or more unvaccinated controls must die for the test to be valid. If these requirement are met, the potency test results are evaluated according to stage one of the following table. The test is inconclusive and may be repeated if the validity requirements are not met, but the serial is unsatisfactory if the test is not repeated.

Stage	Number of vaccinates	Cumulative number of vaccinates	Cummulative total number of dead vaccinates for_____	
			Satisfactory serial	Unsatisfactory serial
1	20	20	6 or less	9 or more.
2	20	40	15 or less ..	16 or more.

(5) The serial shall pass or fail based on the stage one results of the potency test. However, the second stage may be conducted if seven or eight vaccinates die in stage one, but the serial is unsatisfactory if the second stage is not conducted.

(6) The second stage shall be conducted in a manner identical to the first stage. The serial shall be evaluated according to stage two of the table. On the basis of accumulated results from the data of both stage tests, a serial shall either pass or fail the second stage.

[39 FR 16866, May 10, 1974; 39 FR 20368, June 10, 1974, as amended at 40 FR 759, Jan. 3, 1975; 40 FR 23989, June 4, 1975; 47 FR 5195, Feb. 4, 1982; 52 FR 9118, Mar. 23, 1987. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66785, Dec. 26, 1991]

§ 113.118 Pasteurella Multocida Bacterin, Avian Isolate, Type 3.

Pasteurella Multocida Bacterin, Avian Isolate, Type 3, shall be prepared from culture of *Pasteurella multocida,* avian isolate, Type 3 (Little and Lyons classification), which have been inactivated and are nontoxic. Each serial of biological product containing Pasteurella Multocida Bacterin, Avian Isolate, Type 3, 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 shall be tested for viable bacteria and fungi as provided in § 113.26.

(b) *Safety test.* Observation of the vaccinated turkeys during the prechallenge period of the potency test provided in paragraph (c) of this section shall constitute the safety test. If unfavorable reactions that are attributable to the product occur, the serial