Animal and Plant Health Inspection Service, USDA § 113.208

Subserial found unsatisfactory by a prescribed test shall not be released.

(a) Safety test. Bulk samples of completed product from each serial shall be tested for encephalomyelitis virus inactivation.

(1) Each of at least ten 6 to 12 hour old chickens shall be injected subcutaneously with 0.5 ml of the product and the chickens observed each day for 10 days.

(2) If unfavorable reactions attributable to the product occur in the chickens during the observation period, the serial is unsatisfactory. If unfavorable reactions not attributable to the product occur, the test is inconclusive and may be repeated: Provided, That, if the test is not repeated, the serial is unsatisfactory.

(b) Potency test. Bulk or final container samples of completed product from each serial shall be tested for potency in accordance with the two-stage test provided in this paragraph. For each fraction contained in the product—Eastern type, Western type, or Venezuelan type—the serological interpretations required in this test shall be made independently. A serial or subserial found unsatisfactory for any of the fractions shall not be released.

(1) For this test, a guinea pig dose shall be one-half the amount recommended on the label for a horse and shall be administered as recommended for a horse. Each of 10 healthy guinea pigs (vaccinates) shall be injected with two guinea pig doses with an interval of 14 to 21 days between doses. Two additional guinea pigs from the same source shall be held as controls.

(2) Fourteen to 21 days after the second injection, serum samples from each vaccinate and each control shall be tested by a plaque reduction, serum neutralization test using Vero 76 cells.

(3) If the control serum samples show a titer of 1:4 or greater for any fraction, the test is inconclusive for that fraction and may be repeated: Provided, That, if four or more of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction, the serial or subserial is unsatisfactory without further testing.

(4) If two or three of the vaccinate serum samples show a titer of less than 1:40 for the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the second stage of the test may be used for the relevant fraction(s): Provided, That, if a fraction is found acceptable by the first stage of the test, the second stage need not be conducted for that fraction.

(5) If the second stage is used and four or more of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction or the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the serial or subserial is unsatisfactory.

(6) The results shall be evaluated according to the following table:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Vaccinates</th>
<th>Failures for acceptance</th>
<th>Failures for rejection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
<td>1 or less</td>
<td>4 or more</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>3 or less</td>
<td>Do.</td>
</tr>
</tbody>
</table>


§ 113.208 Avian Encephalomyelitis Vaccine, Killed Virus.

Avian Encephalomyelitis Vaccine (Killed Virus) shall be prepared from virus-bearing tissues or fluids obtained from embryonated chicken eggs. Each serial shall meet the general requirements prescribed in §113.200 and the requirements prescribed in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Safety tests. (1) The prechallenge part of the potency test prescribed in paragraph (b) of this section shall constitute a safety test. If any of the vaccinates develop clinical signs of disease or die due to causes attributable to the product, the serial is unsatisfactory.

(2) An inactivation test for viable avian encephalomyelitis (AE) virus shall be conducted on each serial. The test shall be conducted using susceptible chicken embryos: Provided, That, if a non-embryo adapted virus is used for vaccine production, the test shall be conducted in susceptible chickens.
§ 113.209 Rabies Vaccine, Killed Virus.

Rabies Vaccine (Killed Virus) shall be prepared from virus-bearing cell cultures or nerve tissues obtained from animals that have developed rabies infection following injection with rabies virus. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed Virus.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in §113.200 and the requirements prescribed in this section.

(1) Each lot of Master Seed Virus propagated in tissue or cells of avian origin shall also be tested for extraneous pathogens by procedures prescribed in §113.37.

(b) The immunogenicity of vaccine prepared with virus at the highest passage from the Master Seed shall be established in each species for which the vaccine is recommended. Tests shall be conducted in accordance with a protocol filed with Animal and Plant Health Inspection Service before initiation of the tests. The vaccine shall be prepared using methods prescribed in the Outline of Production. If Rabies Vaccine is to be in combination with other fractions, the product to be tested shall include all fractions to be tested.

(1) The preinactivation virus titer must be established as soon as possible after harvest by at least five separate