

Est. 188

Code
2641.00

**OUTLINE OF PRODUCTION
FOR
ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN**

Code 2641.00

Supersedes Outline Dated November 25, 1983
and
Pages 11, 14 and 20 Dated August 19, 1985
and
Pages 15, 16, 16A, 18, 19, 19A, Dated October 31, 1989

Date November 13, 1989

COLORADO SERUM COMPANY
4950 York St-Box 16428
Denver, Colorado 80216

U.S. Vet. License No. 188

REC'D VBFO APR 04 '90

FOIA 10-560.00001



ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN

Code 2641.00
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License No. 188

October 14, 1996
Supersedes Page 20
Dated November 13, 1989

IV. continued

- I. Amount of antigenic material per dose or doses in final containers.

Completed bacterin consists of approximately equal volumes of inactivated cultures of four to six strains (see Section I C). Inactivated cultures account for approximately 63% of the total volume of bacterin. 2 1/2% Aluminum hydroxide accounts for approximately 36% of the total and 1% thimerosal solution accounts for the remaining 1% of the total.

The inactivated culture fraction that comprises approximately 63% of the volume of the bacterin is prepared as per Section IV D.

V. TESTING

Indicate the stages in the preparation of the biological product at which the samples are collected. Refer to all applicable Standard Requirements. Outline all additional tests in detail and state the minimum requirements for each satisfactory test.

- A. Purity.

Final container product, including fifteen and thirty gallon containers "For Export Only" will be tested for purity according to 9 CFR 113.26.

Test Medium Volumes

113.26(a)(2) - Thioglycollate 55-60 ml per vessel.
113.26(a)(3) - Thioglycollate 55-60 ml per vessel.

Disposition will be as indicated therein.

- B. Safety.

Bulk or final container samples of completed product will be tested for safety as provided in Section 113.38 of 9 CFR. Unfavorable reaction attributable to the product should not be observed in any of the test vessels.

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Authorized Representative

REC'D CVB-IC

JAN 16 1997

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LICENSING & POLICY
DEVELOPMENT
NO ENDORSEMENT EXPRESSED

ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN

Code 2641.00
U.S. Veterinary
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August 22, 2005
Supersedes Page 21 Dated
October 30, 1996

V. continued

C. Potency.

Bulk or final container samples of completed product will be tested for potency according to the provisions of 9 CFR 113.119. Determination of satisfactory or unsatisfactory test will be as detailed therein.

D. Moisture, if desiccated.

Not applicable.

E. Other tests.

Residual { Residual free formaldehyde content shall not exceed 0.74 grams per liter when measured by the ferric chloride method in accordance with 9 CFR 113.100 (f).

VI. POST PREPARATORY STEPS

A. Form and size of final containers in which the product is to be distributed.

1. Form of final containers.

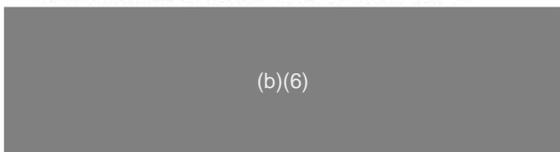
See Special Outline No. 28. "Export Only" containers are autoclavable plastic.

2. Size of final containers.

Bottles are usually referred to as 30 ml, 60 ml, 120 ml, 250 ml, and 500 ml.

Containers for "Export Only" are 15 and 30 gallon.

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