

Ext. 1/12

Code
12G5.10

OUTLINE OF PRODUCTION
BURSAL DISEASE - NEWCASTLE DISEASE VACCINE, KILLED VIRUS

VS Code 12G5.10

COMPLETE REVISION

June 16, 2000

Not on
summary
of Chgs

[Cover Page updated on April 24, 2002, to change company name.] - added
Deleted Replaces the Outline dated November 7, 1997, . . .

[Wyeth] ~~is~~ from American Home Products Corporation
with its producing subsidiaries.

U. S. Veterinary License No. 112

FILED with
USDA-APHIS-VS
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BIOLOGICS

MAY 22 2002

LICENSING & POLICY
DEVELOPMENT
NO ENDORSEMENT
EXPRESSED

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5-20-02

#6
RAK

944

OUTLINE OF PRODUCTION
BURSAL DISEASE - NEWCASTLE DISEASE VACCINE, KILLED VIRUS ✓

U.S. Veterinary License No. 112

VS Code 12G5.10 ✓

December 6, 2006
Supersedes June 16, 2000 ✓

IV. G. Method and Technique of Filling and Sealing of Final Containers ✓

(b) (4)

H. Desiccation ✓

N/A ✓

I. Amount of Antigenic Material Per Dose(s) in Final Container ✓

(b) (4)

V. TESTING ✓

A. Purity ✓

1. Final container samples of completed product from each serial shall be tested in accordance with 9 CFR 113.26 using (b) (4) tryptic Soy Broth at 20-25°C and (b) (4) Thioglycollate at 30-35°C. (APHIS approval granted on March 16, 2006) *APIS approval granted on March 16, 2006. Samples bottles may contain less than 200mg.* (b) (4)
2. Samples of the Newcastle Disease Virus Harvest Fluids shall be tested for Salmonella in accordance with 9 CFR 113.30. ✓
3. Mycoplasma organisms have been shown to be effectively inactivated by (b) (4)
4. Lymphoid Leukosis Viruses have been shown to be effectively inactivated (b) (4)

B. Safety ✓

Bulk or final container samples shall be tested for safety in accordance with 9 CFR 113.205 and 9 CFR 113.212. ✓

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OUTLINE OF PRODUCTION
BURSAL DISEASE - NEWCASTLE DISEASE VACCINE, KILLED VIRUS

U.S. Veterinary License No. 112

VS Code 12G5.10

June 16, 2000

V. C. Potency

1. Bursal Disease Vaccine Fraction

(b) (4)

Bulk or final container samples of the completed product shall be tested in accordance with 9 CFR 113.212.

2. Newcastle Disease Vaccine Fraction:

(b) (4)

Bulk or final container samples of the completed product shall be tested in accordance with 9 CFR 113.205.

D. Moisture, if Desiccated *added*

N/A

E. Any Other Tests *added*

(b) (4)

~~VI.~~ POST-PREPARATORY STEPS

(b) (4)

B.

(b) (4)

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Ext. 112

Code
1705.10

OUTLINE OF PRODUCTION
NEWCASTLE DISEASE VACCINE,
KILLED VIRUS

VS Code 1705.10

COMPLETE REVISION

August 23, 2000

not on summary of changes { [Cover Page updated on April 24, 2002, to change company name.] added
[Added Emphasis to the Outline dated November 11, 1997, ...]

[Wyeth] - *chg from "American Home Products Corporation"*
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MAY 22 2002

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#6
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9/17

OUTLINE OF PRODUCTION
NEWCASTLE DISEASE VACCINE,
KILLED VIRUS ✓

U.S. Veterinary License No. 112

VS Code 1705.10 ✓

December 6, 2006
Supersedes August 23, 2000 ✓

V. TESTING ✓

A. Purity ✓

1. Final container samples of the completed product from each serial shall be tested in accordance with 9 CFR 113.26 using (b) (4) Tryptic Soy Broth at 20-25°C and (b) (4) Thioglycollate at 30-35°C. APHIS approval granted on March 16, 2006. *Added*
2. Bulk samples, prior to inactivation, shall be tested for the following: -
 - a. Salmonella in accordance with 9 CFR 113.30. -
 - b. Mycoplasma organisms have been shown to be effectively inactivated by (b) (4) and no testing is conducted. -
 - c. Lymphoid Leukosis Viruses have been shown to be effectively inactivated by (b) (4) and no testing is conducted. ✓

B. Safety ✓

Safety testing is conducted in accordance with 9 CFR 113.205(a). ✓

C. Potency

Bulk or final container samples of the completed product shall be tested in accordance with 9 CFR 113.205(b) except that serials produced for day-of-age administration will be identified and these serials will be tested (b) (4) using 0.1 mL dose. All other serials will be tested in 2-6 week-old chickens, using 0.3 mL dose. (b) (4)

(b) (4)

D. Moisture, if Desiccated

N/A ✓

12/13/06

#6333

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b6,

OUTLINE OF PRODUCTION
NEWCASTLE DISEASE VACCINE,
KILLED VIRUS

June 25, 2004
Supersedes August 23, 2000 ✓

U.S. Veterinary License No. 112

VS Code 1705.10

V. E. Any Other Tests

from "The residual-free
Formaldehyde... SID"

(b) (4)

VI. POST-PREPARATORY STEPS

(b) (4)

(b) (4)

(b) (4)

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JUL 14 2004

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7/14/04
#003
July 14, 2004
JH 1

Text 112

Code
1711.10

OUTLINE OF PRODUCTION
NEWCASTLE DISEASE VACCINE
B₁ TYPE, B₁ STRAIN
LIVE VIRUS

Chg from "Product"
VS Code 1711.10

COMPLETE REVISION

April 10, 2002

Replaces the Outline dated January 6, 1998, inclusive of subsequent revisions.

} revised

Wyeth *chq*
with its producing subsidiaries.

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MAY 15 2002

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OUTLINE OF PRODUCTION
NEWCASTLE DISEASE VACCINE
B₁ TYPE, B₁ STRAIN
LIVE VIRUS

U.S. Veterinary License No. 112

VS Code 1711.10

June 25, 2004
Supersedes April 10, 2002 ✓

IV. F. Volume of Fill for Each Size Vial

(b) (4)

G. Method and Technique of Filling and Sealing of Final Containers

The product is gross filtered through a sterile 200-500 micron filter element and filled under conditions specified in 9 CFR 114.6 into sterile final containers in a room designated for filling operations. The stoppers are mechanically or manually partially inserted and after lyophilization, stoppers are seated and aluminum seals are applied.

H. Desiccation

1. Frozen vaccine bottles shall be stored at -20°C or colder for no more than 72 hours prior to lyophilization. The vaccine will be dried under vacuum for no more than (b) (4). The maximum product temperature permitted during the cycle shall be 37°C (b) (4). (b) (4) The stoppers are mechanically seated under vacuum. The bottles are then removed from the drier and are capped with aluminum seals.

2. Residual moisture content will be determined in accordance with 9 CFR 113.29 and will not exceed 5%. In the event an individual assay is found to exceed the limit, the test may be repeated in duplicate. The mean of the three assays is calculated. If the first assay is found to be more than two standard deviations away from the mean, then only the two retests will be used in calculation of final mean moisture determination of the serial.

from "Moisture is determined... 5%"
(ref. to S.A. #1009)

(b) (4)

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b6, [redacted] July [redacted]

b6, [redacted]

Page 5
 OUTLINE OF PRODUCTION
 NEWCASTLE DISEASE VACCINE
 B₁ TYPE, B₁ STRAIN
 LIVE VIRUS

U.S. Veterinary License No. 112

VS Code 1711.10

September 30, 2009
 Supersedes February 28, 2007 ✓

V. TESTING

A. Purity

1. The bulk fluid samples are tested for Salmonella in accordance with 9 CFR 113.30.
2. Bulk pooled material, or final container samples shall be tested for Lymphoid Leukosis viruses in accordance with 9 CFR 113.31.
3. Final container samples shall be tested for the following:
 - a. Bacteria and Fungi in accordance with 9 CFR 113.27 using (b) (4) Brain Heart Infusion Agar at 20-25°C and (b) (4) at 30-35°C. USDA approval granted March 10, 2006.
 - b. Mycoplasma in accordance with 9 CFR 113.28 on the first subserial.
 - c. Extraneous pathogens in accordance with 9 CFR 113.37 on the first subserial.
 - d. Identity in accordance with 9 CFR 113.300 on the first subserial.

✓ additions }

B. Safety

Safety testing of the final containers samples shall be conducted in accordance with 9 CFR 113.329(d)(2).

C. Potency

1. Final container samples shall be titrated in accordance with 9 CFR 113.329.
2. Master Seed Immunogenicity Information

Immunogenicity	Newcastle B ₁ B ₁ Eyedrop	Newcastle B ₁ B ₁ Spray
Vaccine Titer	(b) (4)	(b) (4)
Species	Chickens	Chickens
Age	Day of Age	4 Weeks
APHIS Approval	6/28/76	6/28/76 with

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OCT 13 2009

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NC #0033
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 RTG - OCT 8, 2009 - 038

OUTLINE OF PRODUCTION
NEWCASTLE DISEASE VACCINE
B₁ TYPE, B₁ STRAIN
LIVE VIRUS

U.S. Veterinary License No. 112

VS Code 1711.10

April 10, 2002

V. C. ^{was 3} (3) Immunogenicity Testing

- a. The Master Seed ("X+5") immunogenicity testing was completed on May 18, 1976.
- b. The ³⁻three-year repeat immunogenicity testing was completed on July 12, 1979.
- c. The titer of the Master Seed ("X+5") used in the repeat immunogenicity testing (b) (4)
- d. The three year repeat testing was approved by APHIS-USDA on September 28, 1979.

^{was 3} (4) The vaccine titer at release shall be no less than (b) (4) per dose.

^{was 4} (5) The vaccine titer throughout the expiration date shall be no less than (b) (4)

D. Moisture, if Desiccated

[Refer to Section IV. H. of this Production Outline.] - *changed from "N/A"*

added E. Any Other Tests

N/A

VI. POST-PREPARATORY STEPS

(b) (4)

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