

§ 114.10

9 CFR Ch. I (1-1-99 Edition)

3. Minimum and maximum acceptable fill volumes for each final container of reagent included in the kit.

4. The disposition of unsatisfactory material.

V. Testing

Refer to all applicable standard requirements.

A. Purity.

Describe all tests of the kit for purity or specify the exemption as provided in 9 CFR 113.4.

B. Safety.

In vitro products are exempt from safety tests.

C. Potency.

Provide details of tests used to determine the relative reactivity of the kit including minimum requirements for a satisfactory test. Reference standards and control serum used for this purpose should be identified by unique codes or lot numbers.

VI. Postpreparatory Steps

A. Describe the form and size of final containers of each reagent/component included in the kit.

B. Describe the collection, storage, and submission of representative samples. Refer to 9 CFR 113.3(b)(7).

C. Specify the expiration date. Refer to 9 CFR 114.13.

D. Provide details of recommendations for use, including all limitations, qualifications, and interpretation of results.

E. Submit confidentiality statement identifying specific parts of the outline containing information, the release of which would cause harm to the submitter.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16869, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 20124, May 2, 1991; 56 FR 66784, Dec. 26, 1991]

§ 114.10 Antibiotics as preservatives.

Antibiotics are authorized for use as preservatives for biological products if used within the limitations as to kinds and amounts prescribed in this section.

(a) When an antibiotic or combination of antibiotics, with or without a fungistat is to be used in the preparation of a biological product, the kind(s) and amount(s) of each shall be specified in the outline for such product in such a way that the concentration in the final product may be calculated. Except as may be approved by the Administrator, only those individual antibiotics or combinations of antibiotics

listed in paragraphs (b) and (c) of this section shall be used.

(b) Permitted individual antibiotics:

(1) The antibiotic level of a specified individual antibiotic in one ml. of a biological product, when prepared as recommended for use, shall not exceed the amounts listed in this paragraph: *Provided*, That in the case a desiccated biological product is to be used with an indefinite quantity of water or other menstruum, the determination shall be based on 30 ml. per 1,000 dose vial or equivalent.

(2) Except as prescribed in paragraph (c) of this section, only one antibiotic shall be used as a preservative in a biological product. The kind and maximum amount per ml. of such antibiotic shall be restricted to:

Amphotericin B	2.5 mcg.
Nystatin (Mycostatin)	30.0 units
Tetracyclines	30.0 mcg.
Penicillin	30.0 units
Streptomycin	30.0 mcg.
Polymyxin B	30.0 mcg.
Neomycin	30.0 mcg.
Gentamicin	30.0 mcg.

(c) Permitted combinations:

(1) Penicillin and streptomycin.

(2) Either amphotericin B or nystatin, but not both, may be used with one of the other antibiotics listed in paragraph (b) of this section, or with a combination of penicillin and streptomycin, or with a combination of polymyxin B and neomycin.

(3) The maximum amount of each antibiotic in a combination shall be the amount prescribed for such antibiotic in paragraph (b) of this section.

(d) Antibiotics used in virus seed stock purification are not restricted as to kind or amounts provided carryover into the final product is controlled and specified in outlines of production.

[39 FR 16869, May 10, 1974, as amended at 56 FR 66784, Dec. 26, 1991]

§ 114.11 Storage and handling.

Biological products at licensed establishments shall be protected at all times against improper storage and handling. Completed product shall be kept under refrigeration at 35° to 45° F. (2° to 7° C.) unless the inherent nature of the product makes storage at a different temperature advisable, in which case, the proper storage temperature shall be specified in the filed Outline of