

the certification requirements of section 512(n) of the act, if such drugs are licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682; 42 U.S.C. 201 et seq.) or under the Virus-Serum-Toxin Act of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.).

§ 433.23 Microbiological culture media containing antibiotics.

Microbiological culture media that contain any certifiable antibiotic drug subject to the regulations in this chapter shall be exempt from the requirements of sections 502(l) and 507 of the act and the certification requirements of section 512(n) of the act if:

(a) They are intended for use in tissue culture and the antibiotic drug is added solely for use as an aid in the prevention of microbial contamination; or

(b) They are intended for use in the isolation of selected organisms from mixed cultures and the antibiotic drug is added solely for use as an aid in such isolation; and

(c) The certifiable antibiotic drug used in such culture media complies with the applicable standards of identity, strength, quality, and purity prescribed therefor.

§ 433.24 Exemption of antibiotic drugs for use in teaching, law enforcement, research, and analysis.

Antibiotic drugs subject to section 507 or 512(n) of the act shall be exempt from the requirements of section 502(l) and from the certification requirements of section 512(n) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use; or in law enforcement; or in research not involving clinical use; or in chemical analysis or physical testing, provided they are to be used only for such instruction, law enforcement, research, analysis, or testing, and provided further that their labels bear the statement "Not for drug use."

§ 433.25 [Reserved]

§ 433.26 Neomycin sulfate ointment intended for hypersensitivity testing.

Neomycin sulfate ointment subject to sections 502(l) and 507 of the act and

packaged for use as an allergen for skin patch testing of hypersensitivity shall be exempt from the certification requirements of section 502(l) and 507 of the act if it complies with all the following conditions:

(a) It contains neomycin sulfate equivalent to 200 milligrams of neomycin per gram in petrolatum.

(b) The neomycin sulfate used in preparing the neomycin sulfate ointment conforms to the standards prescribed by § 444.42(a)(1) of this chapter except § 444.42(a)(1)(ii).

(c) The shipment of neomycin sulfate is made as a result of a specific request made to the manufacturer or distributor by a practitioner licensed by law to administer such drug, and the use of neomycin sulfate ointment for patch testing is not promoted by the manufacturer or distributor.

(d) Each package shall bear on its outside wrapper or container and on the immediate container, in addition to other labeling information required by the act and regulations, the following statements in lieu of adequate directions for use:

(1) The statement, "Caution: Federal law prohibits dispensing without prescription".

(2) The statement, "For use only in patch testing".

(3) The potency of the ointment.

(4) The expiration date as prescribed by § 432.5(a)(3) of this chapter.

(e) The quantity shipped is limited to an amount reasonable for the purpose of patch testing in the normal course of the practice of medicine and is used solely for such patch testing.

(f) The manufacturer or distributor maintains records of all shipments for this purpose for a period of 2 years after shipment and will make them available to the Food and Drug Administration upon request.

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Subpart D—Records and Reports

§ 433.30 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 433, photostatic or other permanent reproductions may be substituted for such

records after the first 2 years of the holding period.

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

Sec.

Subpart A—Definitions; Interpretations; Requirements

- 436.1 Sterility requirements of items packaged with sterile antibiotic drugs.
436.2 Alternative assay methods.

Subpart B—Sterility Test Methods

- 436.20 Sterility test methods and procedures.

Subpart C—Biological Test Methods

- 436.31 Equipment and diluents for use in biological testing.
436.32 Pyrogen test.
436.35 Depressor substances test.

Subpart D—Microbiological Assay Methods

- 436.100 Laboratory equipment.
436.101 Solutions.
436.102 Culture media.
436.103 Test organisms.
436.104 Penicillin activity.
436.105 Microbiological agar diffusion assay.
436.106 Microbiological turbidimetric assay.

Subpart E—General Chemical Tests for Antibiotics

- 436.200 Loss on drying.
436.201 Moisture determination.
436.202 pH.
436.203 Crystallinity.
436.204 Iodometric assay.
436.205 Hydroxylamine colorimetric assay.
436.206 Test for metal particles in ophthalmic ointments.
436.207 Residue on ignition.
436.208 Heavy metals determination.
436.209 Melting range or temperature.
436.210 Specific rotation.
436.211 Identity tests by infrared spectrophotometry.
436.212 Disintegration test.
436.213 Nonaqueous titrations.
436.214 Heat stability.
436.215 Dissolution test.
436.216 High-performance liquid chromatographic assay.
436.217 Film-coat rupture test.

Subpart F—Chemical Tests for Specific Antibiotics

- 436.300 Polarimetric assay of carbenicillin indanyl sodium.
436.301 Thin layer chromatography identity test for carbenicillin indanyl.
436.302 Clindamycin vapor phase chromatography.
436.303 Clindamycin content of clindamycin palmitate hydrochloride by vapor phase chromatography.
436.304 Clindamycin phosphate vapor phase chromatography.
436.305 Thin layer chromatographic identity test for hetacillin.
436.306 Lincomycin gas liquid chromatography.
436.307 Spectinomycin vapor phase chromatography.
436.308 Paper chromatography identity test for tetracyclines.
436.309 Anhydrotetracyclines and 4-epianhydrotetracycline.
436.310 Thin layer chromatography identity test for mitomycin.
436.311 Thin layer chromatography identity test for amoxicillin.
436.312 Atomic absorption method for determining the zinc content of zinc bacitracin.
436.316 Determination of penicillin G content.
436.317 Solubility characteristic test for griseofulvin (ultramicrosize) tablets.
436.318 Continuous flow thin layer chromatography identity test.
436.319 Thin layer chromatography identity test for bacitracin and bacitracin zinc.
436.320 Ferric chloride colorimetric assay.
436.321 Griseofulvin gas liquid chromatography.
436.322 High-pressure liquid chromatographic assay for anthracycline antibiotics.
436.323 Continuous flow thin layer chromatography identity test for cefamandole nafate.
436.324 Polarographic analysis of cefamandole.
436.325 High pressure liquid chromatography assay for vidarabine.
436.326 Thin layer chromatographic identity test for cefoxitin sodium.
436.327 Thin layer chromatographic identity test for cyclacillin.
436.328 High pressure liquid chromatographic assay for sulfisoxazole acetyl content.
436.329 High-pressure liquid chromatographic assay for meclocycline.
436.330 Thin layer chromatographic identity test for bacampicillin.
436.331 High-pressure liquid chromatographic assay for dactinomycin.
436.332 High-pressure liquid