Subpart D—Testing Procedures

343.90 Dissolution and drug release testing.


SOURCE: 63 FR 56814, Oct. 23, 1998, unless otherwise noted.

Subpart A—General Provisions

§ 343.1 Scope.
(a) An over-the-counter analgesic-antipyretic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in §330.1 of this chapter.
(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 343.3 Definitions.
As used in this part:

Analgesic—antipyretic drug. An agent used to alleviate pain and to reduce fever.

Cardiovascular drug. An agent used to prevent ischemic events.

Rheumatologic drug. An agent used for the treatment of rheumatologic disorders.

Subpart B—Active Ingredients

§ 343.10 [Reserved]

§ 343.12 Cardiovascular active ingredients.
(a) Aspirin.
(b) Buffered aspirin. Aspirin identified in paragraph (a) of this section may be buffered with any antacid ingredient(s) identified in §331.11 of this chapter provided that the finished product contains at least 1.9 milli-equivalents of acid-neutralizing capacity per 325 milligrams of aspirin as measured by the procedure provided in the United States Pharmacopeia 23/National Formulary 18.

§ 343.13 Rheumatologic active ingredients.
(a) Aspirin.
(b) Buffered aspirin. Aspirin identified in paragraph (a) of this section may be buffered with any antacid ingredient(s) identified in §331.11 of this chapter provided that the finished product contains at least 1.9 milli-equivalents of acid-neutralizing capacity per 325 milligrams of aspirin as measured by the procedure provided in the United States Pharmacopeia 23/National Formulary 18.

Subpart C—Labeling

§§ 343.50–343.60 [Reserved]

§ 343.80 Professional labeling.
The labeling of an over-the-counter drug product written for health professionals (but not for the general public) shall consist of the following:
(a) For products containing aspirin identified in §§343.12 and 343.13 or permitted combinations identified in §343.22. (These products must meet United States Pharmacopeia (USP) standards for dissolution or drug release in §343.90.)
(1) The labeling contains the following prescribing information under the heading “Comprehensive Prescribing Information” and the subheadings “Description,” “Clinical Pharmacology,” “Clinical Studies,” “Animal Toxicology,” “Indications and Usage,” “Contraindications,” “Warnings,” “Precautions,” “Adverse Reactions,” “Drug Abuse and Dependence,” “Overdosage,” “Dosage and Administration,” and “How Supplied” in the