Subpart D—Testing Procedures

§ 343.90 Dissolution and drug release testing.

(a) [Reserved]

(b) Aspirin capsules. Aspirin capsules must meet the dissolution standard for aspirin capsules as contained in the United States Pharmacopeia (USP) 23 at page 132.

(c) Aspirin delayed-release capsules and aspirin delayed-release tablets. Aspirin delayed-release capsules and aspirin delayed-release tablets must meet the drug release standard for aspirin delayed-release capsules and aspirin delayed-release tablets as contained in USP 23 at pages 133 and 136 respectively.

(d) Aspirin tablets. Aspirin tablets must meet the dissolution standard for aspirin tablets as contained in USP 23 at page 134.

(e) Aspirin, alumina, and magnesia tablets. Aspirin in combination with alumina and magnesia in a tablet dosage form must meet the dissolution standard for aspirin, alumina, and magnesia tablets as contained in USP 23 at page 138.

(f) Aspirin, alumina, and magnesium oxide tablets. Aspirin in combination with alumina, and magnesium oxide in a tablet dosage form must meet the dissolution standard for aspirin, alumina, and magnesium tablets as contained in USP 23 at page 139.

(g) Aspirin effervescent tablets for oral solution. Aspirin effervescent tablets for oral solution must meet the dissolution standard for aspirin effervescent tablets for oral solution as contained in USP 23 at page 137.

(h) Buffered aspirin tablets. Buffered aspirin tablets must meet the dissolution standard for buffered aspirin tablets as contained in USP 23 at page 135.