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Aspirin, Codeine Phosphate, Alumina, and Magnesia Tablets

» Aspirin, Codeine Phosphate, Alumina, and Magnesia Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of aspirin ($C_9H_8O_4$), codeine phosphate hemihydrate ($C_{18}H_{21}NO_3 \cdot H_3PO_4 \cdot ½H_2O$), aluminum hydroxide [$Al(OH)_3$], and magnesium hydroxide [$Mg(OH)_2$].

Packaging and storage—Preserve in well-closed, light-resistant containers.

USP Reference standards ⟨11⟩—
USP Aspirin RS
USP Codeine Phosphate RS
USP Salicylic Acid RS

Identification—

A: Tablets respond to the *Identification* test under *Aspirin and Codeine Phosphate Tablets*.

B: Tablets respond to the *Identification* tests under *Alumina and Magnesia Tablets*.

Dissolution ⟨711⟩—

Medium: 0.05 M acetate buffer, prepared by mixing 2.99 g of sodium acetate trihydrate and 1.66 mL of glacial acetic acid with water to obtain 1000 mL of solution having a pH of 4.50 ± 0.05; 900 mL.

Apparatus 2: 75 rpm.

Time: 30 minutes.

Mobile phase, Internal standard solution, Solvent mixture, Aspirin and *codeine phosphate standard preparation, Standard solution A, Standard solution B, Standard preparations A* and *B, Test preparation, Chromatographic system,* and *Procedure*—Proceed as directed in the test for *Dissolution* under *Aspirin and Codeine Phosphate Tablets*.

Tolerances—Not less than 75% *(Q)* of the labeled amounts of aspirin ($C_9H_8O_4$) and codeine phosphate hemihydrate ($C_{18}H_{21}NO_3 \cdot H_3PO_4 \cdot ½H_2O$) are dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements for *Content Uniformity* with respect to aspirin and codeine phosphate and for *Weight Variation* with respect to aluminum hydroxide and magnesium hydroxide.

Acid-neutralizing capacity ⟨301⟩: not less than 1.9 mEq per Tablet.

Assay for aspirin and codeine phosphate and limit of free salicylic acid—

Mobile phase, Solvent mixture, Salicylic acid stock standard solution, Salicylic acid standard preparation, Aspirin and *codeine phosphate standard preparation,* and *Chromatographic system*—Prepare as directed in the *Assay for aspirin and codeine phosphate and limit of free salicylic acid* under *Aspirin and Codeine Phosphate Tablets*.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 325 mg of aspirin, to a screw-capped, 120-mL bottle, add 5.0 mL of *Internal standard solution* and 45.0 mL of *Solvent mixture*, mix, and sonicate for 2 to 5 minutes. Centrifuge, and use a portion of the resultant clear solution as the *Assay preparation*.

Procedure—Separately inject equal volumes (about 5 µL) of the *Salicylic acid standard preparation*, the *Aspirin and codeine phosphate standard preparation*, and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times for salicylic acid, aspirin, codeine, and phenacetin are about 0.3, 0.5, 0.8, and 1.0, respectively. Calculate the quantity, in mg, of aspirin ($C_9H_8O_4$) in the portion of powdered Tablets taken by the formula:

$$50C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Aspirin RS in the *Aspirin and codeine phosphate standard preparation;* and R_U and R_S are the ratios of the peak responses of aspirin and phenacetin obtained from the *Assay preparation* and the *Aspirin and codeine phosphate standard preparation*, respectively. Calculate the quantity, in mg, of codeine phosphate hemihydrate ($C_{18}H_{21}NO_3 \cdot H_3PO_4 \cdot ½H_2O$), in the portion of powdered Tablets taken by the formula:

$$(406.37/397.37)(50C)(R_U/R_S)$$

in which 406.37 and 397.37 are the molecular weights of codeine phosphate hemihydrate and anhydrous codeine phosphate, respectively; C is the concentration, in mg per mL, of USP Codeine Phosphate RS in the *Aspirin and codeine phosphate standard preparation;* and R_U and R_S are the ratios of the peak responses of codeine phosphate and phenacetin obtained from the *Assay preparation* and the Aspirin and codeine

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phosphate *Standard preparation,* respectively. Calculate the percentage of free salicylic acid in the Tablets taken by the formula:

$$5000(C/a)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Salicylic Acid RS in the *Salicylic acid standard preparation; a* is the quantity, in mg, of aspirin in the portion of Tablets taken, determined as directed above; and R_U and R_S are the ratios of the peak responses of salicylic acid and phenacetin obtained from the *Assay preparation* and the *Salicylic acid standard preparation*, respectively: not more than 3.0% is found.

Assay for aluminum hydroxide—

Edetate disodium titrant—Prepare and standardize as directed in the *Assay* under *Ammonium Alum*.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 600 mg of aluminum hydroxide, to a 150-mL beaker, add 20 mL of water, stir, and slowly add 30 mL of 3 N hydrochloric acid. Heat gently, if necessary, to aid solution, cool, and filter into a 200-mL volumetric flask. Wash the filter with water into the flask, add water to volume, and mix.

Procedure—Pipet 10 mL of *Assay preparation* into a 250-mL beaker, add 20 mL of water, then add, in the order named and with continuous stirring, 25.0 mL of *Edetate disodium titrant* and 20 mL of acetic acid-ammonium acetate buffer TS. Add 50 mL of alcohol and 2 mL of dithizone TS, and mix. Titrate with 0.05 M zinc sulfate VS until the color changes from green-violet to rose-pink. Perform a blank determination, substituting 10 mL of water for the *Assay preparation*, and make any necessary correction. Each mL of 0.05 M Edetate disodium titrant is equivalent to 3.900 mg of $Al(OH)_3$.

Assay for magnesium hydroxide—

Assay preparation—Prepare as directed in the *Assay for aluminum oxide*.

Procedure—Pipet a volume of *Assay preparation*, equivalent to about 40 mg of magnesium hydroxide, into a 400-mL beaker, add 200 mL of water and 20 mL of triethanolamine, and stir. Add 10 mL of ammonia-ammonium chloride buffer TS and 3 drops of an eriochrome black indicator solution prepared by dissolving 200 mg of eriochrome black T in a mixture of 15 mL of triethanolamine and 5 mL of dehydrated alcohol, and mix. Cool the solution to between 3° and 4° by immersion of the beaker in an ice bath, then remove, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Perform a blank determination, substituting 10 mL of water for the *Assay preparation*, and make any necessary correction. Each mL of 0.05 M edetate disodium consumed is equivalent to 2.916 mg of $Mg(OH)_2$.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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