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# Butalbital, Acetaminophen, and Caffeine Capsules

» Butalbital, Acetaminophen, and Caffeine Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of butalbital ($C_{11}H_{16}N_2O_3$), acetaminophen ($C_8H_9NO_2$), and caffeine ($C_8H_{10}N_4O_2$).

**Packaging and storage**—Preserve in tight containers.

**USP Reference standards** ⟨11⟩—

USP Acetaminophen RS
USP Butalbital RS
USP Caffeine RS

**Identification**—The retention times of the butalbital, acetaminophen, and caffeine peaks in the chromatogram of the *Assay preparation* correspond to those of the butalbital, acetaminophen, and caffeine peaks in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

**Dissolution** ⟨711⟩—

*Medium:* water; 900 mL.

*Apparatus 1:* 100 rpm.

*Time:* 60 minutes.

*Mobile phase* and *Chromatographic system*—Prepare as directed in the *Assay* under *Butalbital, Acetaminophen, and Caffeine Tablets.*

*Standard preparation*—Prepare a solution in methanol having known concentrations of about 0.02*A* mg of USP Acetaminophen RS per mL, 0.02*B* mg of USP Butalbital RS per mL, and 0.02*C* mg of USP Caffeine RS per mL, in which *A*, *B*, and *C* are the labeled amounts, in mg of acetaminophen, butalbital, and caffeine, respectively, per Capsule. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix.

*Procedure*—Pass a portion of the solution under test through a filter of 10-µm or finer porosity. Separately inject equal volumes (about 20 µL) of the filtrate and the *Standard preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantities, in mg, of butalbital ($C_{11}H_{16}N_2O_3$), acetaminophen ($C_8H_9NO_2$), and caffeine ($C_8H_{10}N_4O_2$) dissolved by the same formula:

$$900C(r_U/r_S)$$

in which $C$ is the concentration, in mg per mL, of the appropriate USP Reference Standard in the *Standard preparation;* and $r_U$ and $r_S$ are the peak responses of the corresponding analyte obtained from the solution under test and the *Standard preparation*, respectively.

*Tolerances*—Not less than 80% *(Q)* of the labeled amounts of $C_{11}H_{16}N_2O$, $C_8H_9NO_2$, and $C_8H_{10}N_4O_2$ is dissolved in 60 minutes.

**Uniformity of dosage units** ⟨905⟩: meet the requirements.

**Assay**—

*Mobile phase, Internal standard solution, Butalbital standard stock solution, Caffeine standard stock solution, Standard preparation,* and *Chromatographic system*—Proceed as directed in the *Assay* under *Butalbital, Acetaminophen, and Caffeine Tablets.*

*Assay preparation*—Remove, as completely as possible, the contents of not fewer than 20 Capsules. Transfer an accurately weighed portion of the powder, equivalent to about the weight of the contents of 1 Capsule, to a 200-mL volumetric flask, add *Internal standard solution* to volume, and mix. Sonicate for 15 minutes, mix, and allow to cool and settle. Transfer 20.0 mL of the clear supernatant to a 50-mL volumetric flask, dilute with water to volume, and mix. Pass a portion of this solution through a filter of 0.5 µm or finer porosity, discarding the first 5 mL of the filtrate. Use the clear filtrate as the *Assay preparation.*

*Procedure*—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak responses for the major peaks. Calculate the quantities, in mg, of butalbital ($C_{11}H_{16}N_2O_3$), acetaminophen ($C_8H_9NO_2$), and caffeine ($C_8H_{10}N_4O_2$) in the portion of Capsules taken by the formula:

$$500D(R_U/R_S)$$

in which $D$ is the concentration, in mg per mL, of the appropriate USP Reference Standard in the *Standard preparation;* and $R_U$ and $R_S$ are the peak response ratios of the corresponding analyte to phenacetin obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

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**Chromatographic Database Information:** Chromatographic Database

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