**Codeine Sulfate USP Powder**

**ITEM CODE** 1580

![Chemical Structure of Codeine Sulfate](image)

**CAS REGISTRY NO.** 685440-6

**FORMULA** \((C_{18}H_{21}NO_3)_2\cdot H_2SO_4 \cdot 3H_2O\)

**MOLECULAR WEIGHT** 750.86

**APPEARANCE** Fine, white, crystalline powder

**SOLUBILITY** Clear, colorless solution

**IDENTIFICATION**
- (A) IR: Matches reference standard
- (B) UV: 3.0% Max
- (C) Sulfate: White precipitate

**SPECIFIC ROTATION (Anhydrous)** -112.5° to -115.0°

**ACIDITY (AS H_2SO_4)** 0.6 mL Max

**WATER** 6.0 – 7.5%

**READILY CARBONIZABLE SUBSTANCES**

- Color ≤ reference

**RESIDUE ON IGNITION** 0.1% Max

**LIMIT OF MORPHINE**

- No blue color

**CHROMATOGRAPHIC PURITY**

- Meets USP requirements

**ASSAY (C_{18}H_{21}NO_3)_2 \cdot H_2SO_4 (DRIED BASIS)** 98.5 – 100.5%

**RESIDUAL SOLVENTS**

- Meets USP requirements

**HEAVY METALS (as Pb)** 0.002% Max

**COLOR OF SOLUTION** 0.055 Max

**SIEVE TEST US STANDARD NO.170**

- 95% Min through

**BULK (LOOSE)**

- 20 mL per 5 g Max

**ASSAY (HPLC) (DRIED BASIS)**

- 97.0 – 100.5% w/w

**RELATED SUBSTANCES**

- Codeine Methyl Ether (as the sulfate): 1.0% w/w Max
- Morphine: 0.15% w/w Max
- 10-Hydroxycodeine: 0.15% w/w Max
- Codeine N-Oxide: 0.15% w/w Max
- Norcodeine: 0.15% w/w Max
- Codeinone: 0.15% w/w Max
- Unknown rel. subs.: 0.10% w/w Max
- Total rel. subs. (excluding CME): 0.50% w/w Max

**CODEINE PHOSPHATE**

- Salt of codeine alkaloid is a phenanthrene-derivative opiate agonist. Codeine alkaloid is the methyl ether of morphine and is present in opium at approximately 2.5 percent.

Although Codeine Sulfate has analgesic properties, its primary use is as an antitussive.

The substitution of one codeine salt for another does not significantly change the fundamental action of the codeine compound, for pharmacological activity is essentially determined by the alkaloid content. The inorganic portion of the molecule, however, does influence certain physical properties of the salt, such as stability, solubility, rate of solution, crystal form, bulk, crystal size, tableting characteristics and the preferred state of hydration.

Common Trade Names: Codeine Sulfate Tablets USP

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