

Cellulose Acetate Phthalate

1 Nonproprietary Names

BP: Cellacefate

JP: Cellacefate

PhEur: Cellulose Acetate Phthalate

USP–NF: Cellacefate

2 Synonyms

Acetyl phthalyl cellulose; *Aquacoat CPD*; CAP; cellacefate; cellulose acetate benzene-1,2-dicarboxylate; cellulose acetate hydrogen 1,2-benzenedicarboxylate; cellulose acetate hydrogen phthalate; cellulose acetate monophthalate; cellulose acetophthalate; cellulose acetylphthalate; cellulosi acetas phthalas.

3 Chemical Name and CAS Registry Number

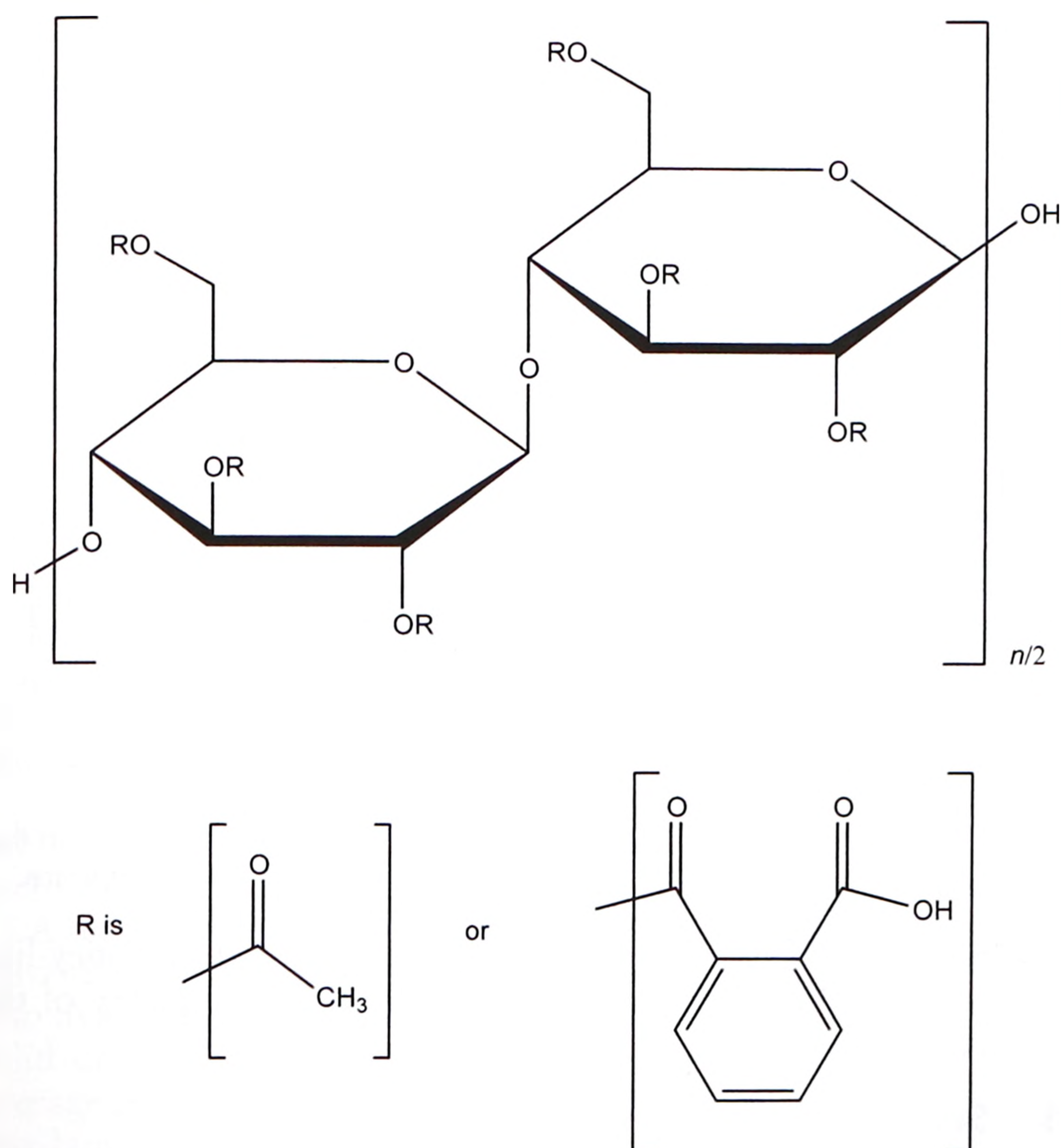
Cellulose, acetate, 1,2-benzenedicarboxylate [9004-38-0]

4 Empirical Formula and Molecular Weight

Cellulose acetate phthalate is a cellulose in which some of the hydroxyl groups are acetylated and some are phthalylated.

5 Structural Formula

Cellulose acetate phthalate is a reaction product of phthalic anhydride and a partial acetate ester of cellulose. It contains 21.5–26.0% of acetyl (C_2H_3O) groups and 30.0–36.0% of phthalyl (*o*-carboxybenzoyl, $C_8H_5O_3$) groups, calculated on the anhydrous acid-free basis.



6 Functional Category

Coating agent; microencapsulating agent; tablet and capsule binder.

7 Applications in Pharmaceutical Formulation or Technology

Cellulose acetate phthalate is used as an enteric film-coating material, as a microencapsulation agent, or as a matrix binder for tablets and capsules.^(1–8) Such coatings resist prolonged contact with the strongly acidic gastric fluid, but dissolve in the mildly acidic or neutral intestinal environment.

Cellulose acetate phthalate is commonly applied to solid-dosage forms either by coating from organic or aqueous solvent systems, or by direct compression. Concentrations generally used are 0.5–9.0% of the core weight. The addition of plasticizers improves the water resistance of this coating material, and formulations using such plasticizers are more effective than when cellulose acetate phthalate is used alone.

Cellulose acetate phthalate is compatible with many plasticizers, including acetylated monoglyceride; butyl phthalylbutyl glycolate; dibutyl tartrate; diethyl phthalate; dimethyl phthalate; ethyl phthalylethyl glycolate; glycerin; propylene glycol; triacetin; triacetin citrate; and tripropionin. It is also used in combination with other coating agents such as ethyl cellulose in controlled-release preparations.

8 Description

Cellulose acetate phthalate occurs as a hygroscopic, white to off-white, free-flowing powder, granule, or flake. It is tasteless and odorless, or might have a slight odor of acetic acid.

9 Pharmacopeial Specifications

The pharmacopeial specifications for cellulose acetate phthalate have undergone harmonization of many attributes for JP, PhEur, and USP–NF.

See Table I. See also Section 18.

Table I: Pharmacopeial specifications for cellulose acetate phthalate.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters ^(a)	+	+	–
Free acid	≤3.0%	≤3.0%	≤3.0%
Heavy metals ^(a)	≤10 ppm	–	≤0.001%
Residue on ignition	≤0.1%	–	≤0.1%
Sulfated ash	–	≤0.1%	–
Viscosity (15% w/v solution)	45–90 mPa s	45.0–90.0 mPa s	45.0–90.0 mPa s
Water	≤5.0%	≤5.0%	≤5.0%
Assay	+	+	+
Acetyl groups	21.5–26.0%	21.5–26.0%	21.5–26.0%
Phthalyl (<i>o</i> -carboxybenzoyl) groups	30.0–36.0%	30.0–36.0%	30.0–36.0%

(a) These tests have not been fully harmonized at the time of publication.

10 Typical Properties

Density (bulk) 0.260 g/cm³

Density (tapped) 0.266 g/cm³

Melting point 192°C. Glass transition temperature is 160–170°C.⁽⁹⁾