Cellaburate

1 Nonproprietary Names

BP: Cellulose Acetate Butyrate

PhEur: Cellulose Acetate Butyrate

USP–NF: Cellaburate

2 Synonyms

Acetylbutyrylcellulose; cellaburatum; cellulose acetate butanoate; cellulose butyrate acetate; cellulosi acetas butyras.

3 Chemical Name and CAS Registry Number

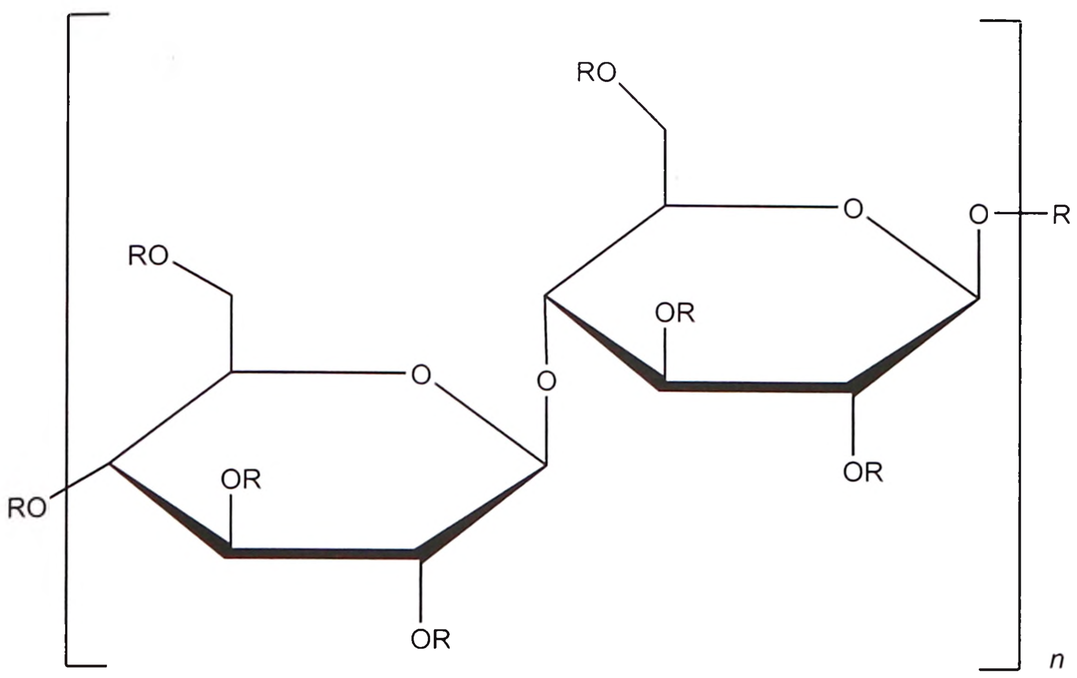
Cellulose acetate butanoate [9004-36-8]

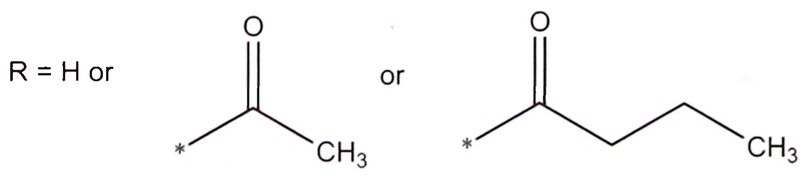
4 Empirical Formula and Molecular Weight

Cellaburate is a cellulose derivative in which between 1% and 41% of the hydroxyl groups are acetylated, and between 5% and 56% of hydroxyl groups are butyrylated.

The PhEur 9.2 describes cellaburate as a partly or completely *O*-acetylated and *O*-butyrylated cellulose containing not less than 2.0% and not more than 30.0% acetyl groups, and not less than 16.0% and not more than 53.0% of butyryl groups, calculated with reference to the dried substance.

5 Structural Formula





6 Functional Category

Coating agent; film-forming agent; membrane-forming agent; modified-release agent; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Cellaburate has been used in the formulation of oral modified-release drug delivery systems.[1] It is an alternative to cellulose acetate as the semipermeable barrier layer in osmotic pump devices.[2] Cellaburate has also been used in controlled release solid dosage forms resistant to alcohol-induced dose dumping.[3]

8 Description

Cellaburate occurs as a white to off-white, slightly hygroscopic powder or granules.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for cellaburate.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Residue on ignition	≤0.1%	≤0.1%
Heavy metals	–	≤0.002%
Free acid	–	≤0.1%
Acidity	+	–
Water determination	–	≤5.0%
Loss on drying	≤2.0%	–
Assay		
C_2H_3O groups	2.0–30.0%	1.0–41.0%
C_4H_7O groups	16.0–53.0%	5.0–56.0%

10 Typical Properties

Density 1.26 g/cm^3

Density (bulk) 0.224 g/cm^3

Density (tapped) 0.256 g/cm^3

Dielectric strength 784–984 kV/cm

Glass transition temperature (T_g) 151°C

Hardness 27 Knoops

Melting point 230–240°C

Refractive index 1.475

Solubility Practically insoluble in water and in ethanol (95%); soluble in acetone, formic acid, and in a mixture of equal volumes of methanol and dichloromethane.

Specific gravity 1.26

11 Stability and Storage Conditions

Slow hydrolysis of cellaburate will occur under prolonged adverse conditions such as high temperatures and high humidity, with a resultant increase in free acid content and water content. Store in airtight containers in a cool, dry place.

12 Incompatibilities

Cellaburate is incompatible with oxidizing materials. Mixing cellulose esters in a nonpolar hydrocarbon, such as toluene or xylene, may result in the buildup of static electricity, which can cause a flash fire or an explosion. When adding cellulose ester to any flammable liquid, an inert gas atmosphere should be maintained within the vessel.

13 Method of Manufacture

Cellaburate is produced by reacting cellulose with acetic anhydride and *n*-butyric anhydride in the presence of a tertiary organic base or a strong acid.