

Hydroxypropyl Starch

1 Nonproprietary Names

PhEur: Starch, Hydroxypropyl
USP-NF: Hydroxypropyl Corn Starch
Hydroxypropyl Pea Starch
Hydroxypropyl Potato Starch

2 Synonyms

Amylum hydroxypropylum; E1440.

3 Chemical Name and CAS Registry Number

Hydroxypropyl starch [113894-92-1]

4 Empirical Formula and Molecular Weight

Hydroxypropyl starch is a derivative of natural starch. It is described in the USP 40-NF 35 S1 and PhEur 9.2 as a partially substituted 2-hydroxypropylether of corn starch, potato starch, tapioca starch, rice starch, or pea starch chemically modified by etherification with the reagent propylene oxide. It may be partially hydrolyzed using acids or enzymes to obtain 'thinned starch' with reduced viscosity

5 Structural Formula

See Section 4.

6 Functional Category

Emulsifying agent; tablet and capsule disintegrant; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Hydroxypropyl starch is a modified starch and has been used in combination with carrageenan in the production of soft capsules.^(1,2) Blends of hydroxypropyl methylcellulose with up to 70% hydroxypropyl starch have been developed for use as hard capsule materials.⁽³⁾ Hydroxypropyl starch is also used widely in cosmetics. See also Section 18.

8 Description

Hydroxypropyl starch occurs as a free-flowing white to off-white coarse powder.

9 Pharmacopeial Specifications

The pharmacopeial specifications for hydroxypropyl cellulose have undergone harmonization of many attributes for JP, PhEur, and USP-NF.

See Table I. See also Section 18.

10 Typical Properties

Acidity/alkalinity pH = 4.5–7.0 (10% w/v aqueous dispersion)
Solubility Practically insoluble in water, ethanol (95%), and ether.

11 Stability and Storage Conditions

Hydroxypropyl starch is stable at high humidity and is considered to be inert under normal conditions. It is stable in emulsion systems at pH 3–9.

Table I: Pharmacopeial specifications for hydroxypropyl starch.

Test	PhEur 9.2	USP 40-NF 35 S1 ^(a)
Identification	+	+
Characters	+	—
pH	4.5–8.0	4.5–8.0
Foreign matter	+	+
Oxidizing substances	≤20 ppm	≤20 µg/g
Sulfur dioxide	≤50 ppm	≤50 ppm
Iron		
Corn, tapioca, potato, or rice starches	≤20 ppm	≤20 µg/g
Pea starch	≤50 ppm	≤50 µg/g
Loss on drying		
Corn, tapioca, pea, or rice starches	≤15.0%	≤15.0%
Potato starch	≤20.0%	≤20.0%
Sulfated ash	≤0.6%	≤0.6%
Microbial contamination		
Bacteria	10 ³ cfu/g	10 ³ cfu/g
Yeasts and molds	10 ² cfu/g	10 ² cfu/g
Assay (dried basis)	0.5–7.0%	2.0–7.0%

(a) USP 40-NF 35 S1 is for hydroxypropyl corn, pea, and potato starches only.

12 Incompatibilities

See Section 18.

13 Method of Manufacture

Hydroxypropyl starch is produced industrially from natural starch, using propylene oxide as the modifying reagent in the presence of alkali, adding hydroxypropyl (CH(OH)CH₂CH₃) groups at the OH positions by an ether linkage.

14 Safety

Hydroxypropyl starch is widely used in cosmetics and food products. It is also used in oral pharmaceutical formulations. The WHO has set an acceptable daily intake for hydroxypropyl starch at 'not limited' since it was well tolerated on oral consumption.⁽⁴⁾

LD₅₀ (rat, oral): 0.218 g/kg⁽⁵⁾

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe.

17 Related Substances

Pregelatinized hydroxypropyl starch; starch; starch, modified.

Pregelatinized hydroxypropyl starch

Synonyms Amylum hydroxypropylum pregelificatum

Description White or slightly yellow powder

Method of manufacture Pregelatinized hydroxypropyl starch is prepared from hydroxypropyl starch by mechanical processing in the presence of water, with or without heat, to rupture all or part of the starch granules, and subsequent drying.