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22 Date of Revision

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Hydroxypropyl Cellulose, Low-substituted

1 Nonproprietary Names

BP: Low-Substituted Hydroxypropylcellulose

JP: Low Substituted Hydroxypropylcellulose

PhEur: Hydroxypropylcellulose, Low-Substituted

USP–NF: Low-Substituted Hydroxypropyl Cellulose

2 Synonyms

Cellulose, 2-hydroxypropyl ether; 2-hydroxypropyl ether (low-substituted) cellulose; hydroxypropylcellulosum substitutum humile; hyplose, low-substituted; *L-HPC*; low-substituted *O*-(2-hydroxypropylated) cellulose; oxypropylated cellulose.

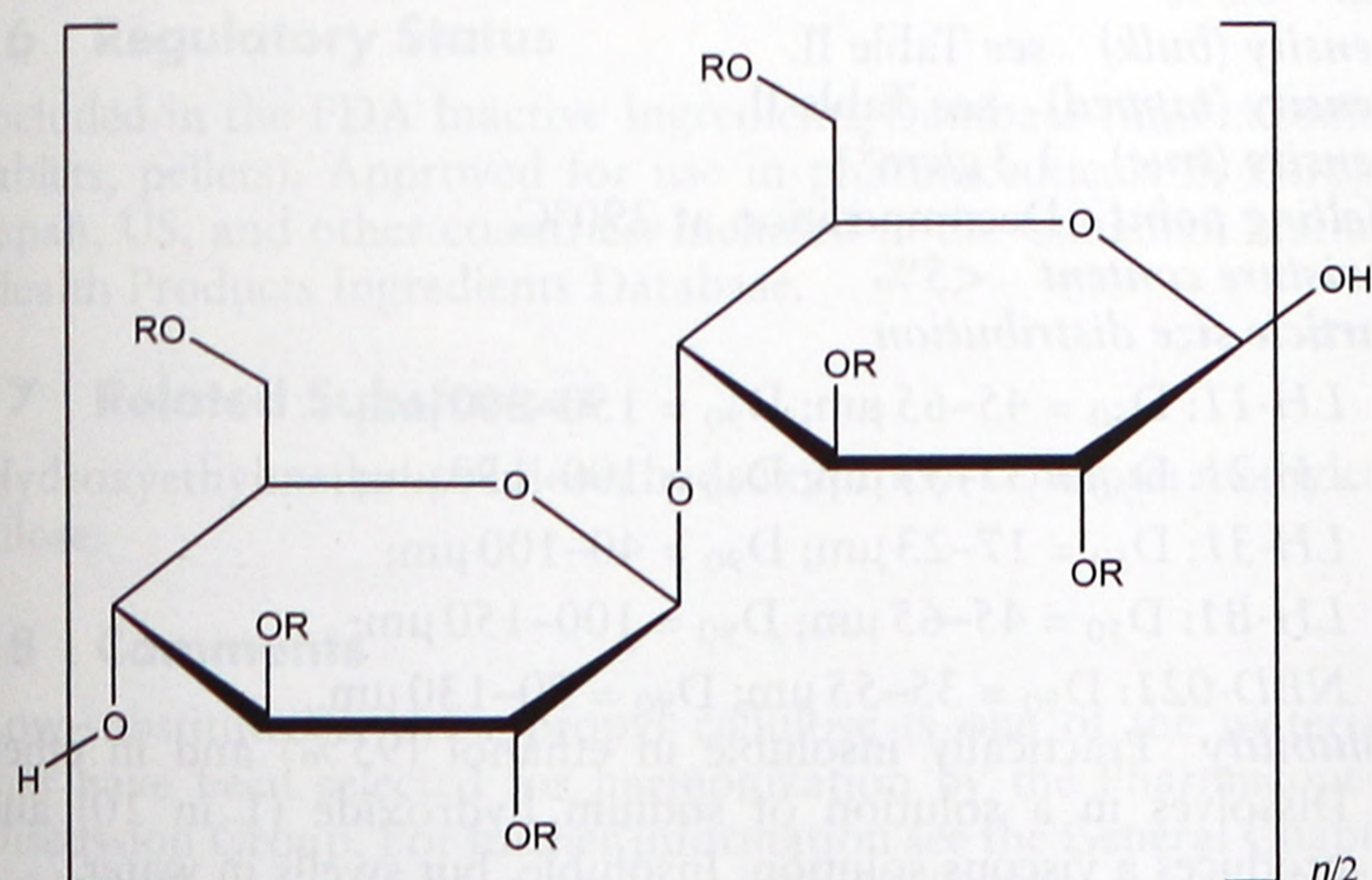
3 Chemical Name and CAS Registry Number

Cellulose, 2-hydroxypropyl ether (low-substituted) [9004-64-2]

4 Empirical Formula and Molecular Weight

The USP 40–NF 35 S1 describes low-substituted hydroxypropyl cellulose as a low-substituted hydroxypropyl ether of cellulose. Compared to hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose has only a small proportion of the three free hydroxyl groups per glucose subunit converted to a hydroxypropyl ether.⁽¹⁾ When dried at 105°C for 1 hour, it contains not less than 5.0% and not more than 16.0% of hydroxypropoxy groups ($-\text{OCH}_2\text{CHOHCH}_3$). Low-substituted hydroxypropyl cellulose is commercially available in a number of different grades that have different particle sizes, shapes and substitution levels.

5 Structural Formula



R is H or $[\text{CH}_2\text{CH}(\text{CH}_3)\text{O}]_m\text{H}$

6 Functional Category

Tablet and capsule binder; tablet and capsule diluent; tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Low-substituted hydroxypropyl cellulose (L-HPC) is widely used in oral solid-dosage forms. It is primarily used as a disintegrant, and as a binder for tablets and granules in wet or dry granulation.⁽¹⁾ It has been used in the preparation of rapidly disintegrating tablets produced by direct compression methods.^(2–4) In addition, L-HPC has been used as a binder/disintegrant included in the powder layering process on spherical cores and to prepare pellets by extrusion/spheronization.^(1,5,6) A low particle size and high hydroxypropyl content is recommended to produce round spheres and rapid dissolution.^(1,7)

The typical content of L-HPC in a formulation is approximately 5–50%.

8 Description

Low-substituted hydroxypropyl cellulose occurs as a white to yellowish white hygroscopic powder or granules. It is odorless or has a slight, characteristic odor, and it is tasteless.

SEM 1: Excipient: low-substituted hydroxypropyl cellulose, type *LH-11*; manufacturer: Shin-Etsu Chemical Co. Ltd.; magnification: 350×; voltage: 3.0 kV.

