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22 Date of Revision

4 May 2017.

Fructose and Pregelatinized Starch, Coprocessed

1 Nonproprietary Names

None adopted.

2 Synonyms

Advantose FS 95.

3 Chemical Name and CAS Registry Number

See Section 8.

4 Empirical Formula and Molecular Weight

See Section 8.

5 Structural Formula

See Section 8.

6 Functional Category

Direct compression excipient; taste-masking agent.

7 Applications in Pharmaceutical Formulation or Technology

Coprocessed fructose and pregelatinized starch is used in the direct compression of tablets to improve flowability and compressibility.⁽¹⁾ Additionally, so-called ‘chewable’ tablets can be prepared using coprocessed fructose and pregelatinized starch.

Coprocessed fructose and pregelatinized starch is also used to mask undesirable flavors of components in tablet formulations.

8 Description

Coprocessed fructose and pregelatinized starch occurs as a white crystalline powder containing 95% fructose and 5% pregelatinized starch (a co-dried system of these two ingredients).⁽¹⁾

9 Pharmacopeial Specifications

Both fructose and pregelatinized starch are listed as separate monographs in the BP 2017, JP XVII (only fructose), PhEur 9.2, and

USP 40–NF 35 S1, but the combination is not listed. See Fructose, and Starch, Pregelatinized.

10 Typical Properties

Angle of repose 12° for *Advantose FS 95*⁽¹⁾

Density (bulk) 0.55–0.75 g/cm³ for *Advantose FS 95*⁽¹⁾

Loss on drying ≤ 2.0% for *Advantose FS 95*⁽²⁾

Moisture content (KF) 1–2% for *Advantose FS 95*⁽¹⁾

Particle size distribution Over 80% of the crystalline powder is retained on a #60 mesh (250 μm) screen for *Advantose FS 95*.⁽¹⁾

Solubility Partially soluble in water for *Advantose FS 95*.⁽²⁾

See also Fructose, and Starch, Pregelatinized.

11 Stability and Storage Conditions

Coprocessed fructose and pregelatinized starch is a chemically stable mixture. Protect from excessive temperatures and humidity. Optimum storage conditions are 25°C and 50% relative humidity. The container should be kept tightly closed and in a cool, well-ventilated place.⁽²⁾

12 Incompatibilities

Coprocessed fructose and pregelatinized starch may react with oxidizing agents.⁽²⁾ Fructose is a reducing sugar and can react with amines, amino acids, peptides, and proteins.

See Fructose, and Starch, Pregelatinized.

13 Method of Manufacture

Coprocessed fructose and pregelatinized starch is prepared by co-drying a mixture of the two ingredients.

14 Safety

Eye contact with coprocessed fructose and pregelatinized starch may produce slight irritation. No skin irritation may be expected from single short-term exposure, although prolonged or repeated contact may produce some irritation. Ingestion of large amounts may produce gastrointestinal disturbances. Overexposure to dusts may produce irritation of the respiratory system.⁽²⁾

See Fructose, and Starch, Pregelatinized.