20 General References

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21 Author

RT Guest.

22 Date of Revision

4 May 2017.

Inulin

1 Nonproprietary Names

BP: Inulin

USP–NF: Inulin

2 Synonyms

Alant starch; alantin; *Beneo*; dahlin; *Frutafit*; oligofructose; *Orafti*; polyfructose; *Raftiline*.

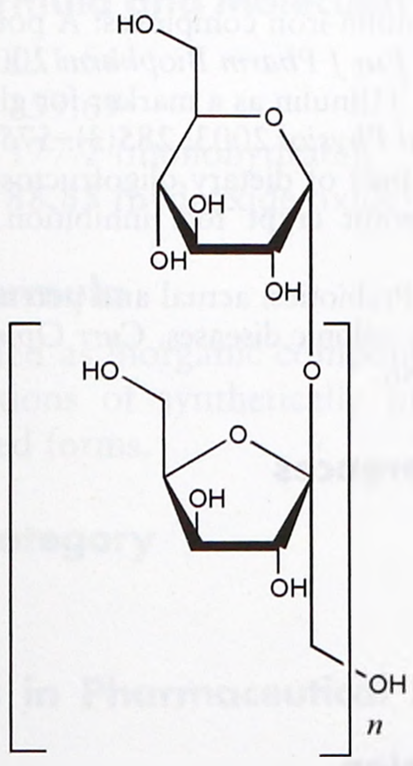
3 Chemical Name and CAS Registry Number

Inulin [9005-80-5]

4 Empirical Formula and Molecular Weight

$C_6H_{11}O_5(C_6H_{11}O_5)_nOH$ ≈5 000

5 Structural Formula



Inulin is a naturally occurring polysaccharide consisting of a linear chain of linked D-fructose molecules, having one terminal glucose molecule.

6 Functional Category

Lyophilization aid; sweetening agent; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Inulin has many potential uses in pharmaceutical applications, as a filler–binder in tablet formulations,[1,2] to stabilize therapeutic proteins,[3,4] vaccines,[5] and PEGylated lipoplexes[6] during freeze-drying, or to enhance the dissolution of lipophilic drugs.[7–9] Inulin has also been used as a stabilizer for recombinant human deoxyribonuclease when spray-dried to produce a powder for inhalation.[10] *See also* Section 18.

Inulin is used in the food industry as a sweetener and stabilizer.

8 Description

Inulin occurs as an odorless, friable, white amorphous powder with a neutral to slightly sweet taste.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for inulin.

Test	BP 2017	USP 40–NF 35 S1
Identification	+	–
Characters	+	–
Acidity	+	4.5–7.0
Clarity and color of solution	+	+
Microbial limit	–	≤1000/g
Loss on drying	≤10.0%	≤10.0%
Specific rotation	–36.5° to –40.5°	–32.0° to –40.0°
Residue on ignition	≤0.1%	≤0.05%
Sulfate	≤200 ppm	≤0.05%
Calcium	≤270 ppm	≤0.1%
Chloride	≤170 ppm	≤0.014%
Iron	–	+
Heavy metals	–	≤5 ppm
Arsenic	≤1 ppm	–
Lead	≤2 ppm	–
Oxalate	+	–
Reducing sugars	+	+
Free fructose	–	+
Content of combined glucose	–	+
Assay (dried basis)	–	94.0–102.0%