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N Culver.

22 Date of Revision

4 May 2017.

Dextrates

1 Nonproprietary Names

USP–NF: Dextrates

2 Synonyms

Candex; dextratos; *Emdex*.

3 Chemical Name and CAS Registry Number

Dextrates [39404-33-6]

4 Empirical Formula and Molecular Weight

The USP 40–NF 35 S1 describes dextrates as a purified mixture of saccharides resulting from the controlled enzymatic hydrolysis of starch. It is either hydrated or anhydrous. Its dextrose equivalent is not less than 93.0% and not more than 99.0%, calculated on the dried basis. In addition to dextrose, dextrates contains 3–5% w/w maltose and higher polysaccharides.

5 Structural Formula

See Section 4.

6 Functional Category

Tablet and capsule binder; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Dextrates is a directly compressible tablet diluent used in chewable, nonchewable, soluble, dispersible, and effervescent tablets.[1–3] Dextrates has been evaluated as diluent in effervescent[4,5] and orally disintegrating tablets.[6] It is a free-flowing material and glidants are thus unnecessary. Lubrication with magnesium stearate (0.5–1.0% w/w) is recommended.[7] Dextrates may also be used as a binding agent by the addition of water, no further binder being required.[7]

Tablets made from dextrates increase in crushing strength in the first few hours after manufacture, but no further increase occurs on storage.[8]

8 Description

Dextrates is a purified mixture of saccharides resulting from the controlled enzymatic hydrolysis of starch. It is either anhydrous or hydrated. In addition to dextrose, dextrates contains 3–5% w/w maltose and higher polysaccharides.

Dextrates comprises white spray-crystallized free-flowing porous spheres. It is odorless with a sweet taste (about half as sweet as sucrose).

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for dextrates.

Test	USP 40–NF 35 S1
pH (20% aqueous solution)	3.8–5.8
Loss on drying	
Anhydrous	≤2.0%
Hydrated	7.8–9.2%
Residue on ignition	≤0.1%
Heavy metals	≤5 ppm
Dextrose equivalent (dried basis)	93.0–99.0%

10 Typical Properties

Angle of repose 26.4° [9]
Compressibility *see* Figure 1.[9]
Density (bulk) 0.68 g/cm^3 [9]
Density (tapped) 0.72 g/cm^3 [9]
Density (true) 1.539 g/cm^9
Hausner ratio 1.05
Flowability 9.3 g/s [9]
Heat of combustion 16.8–18.8 J/g (4.0–4.5 cal/g)
Heat of solution −105 J/g (−25 cal/g)
Melting point 141°C
Moisture content 7.8–9.2% w/w (hydrated form). *See also* Figure 2.[10]
Particle size distribution Not more than 3% retained on a 840 μm sieve; not more than 25% passes through a 150 μm sieve. Mean particle size 190–220 μm.