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21 Authors

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22 Date of Revision

4 May 2017.

Lactose Monohydrate and Corn Starch, Coprocessed

1 Nonproprietary Names

None adopted.

2 Synonyms

StarLac.

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; tablet and capsule diluent; tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Coprocessed lactose monohydrate and corn starch can be used in tablets to improve compressibility, powder flow, and disintegration properties.[1] In addition to its traditional low- to mid-dose pharmaceutical formulation applications, it is used in homeopathic formulations to enable direct compression.

8 Description

Coprocessed α-lactose monohydrate and corn starch occurs as a white to nearly white odorless powder comprising of 82–88% lactose monohydrate and 12–18% corn (maize) starch in an integrated particle, which cannot be achieved via simple blending. It is a free-flowing powder owing to its spherical structure and typical median particle size.

9 Pharmacopeial Specifications

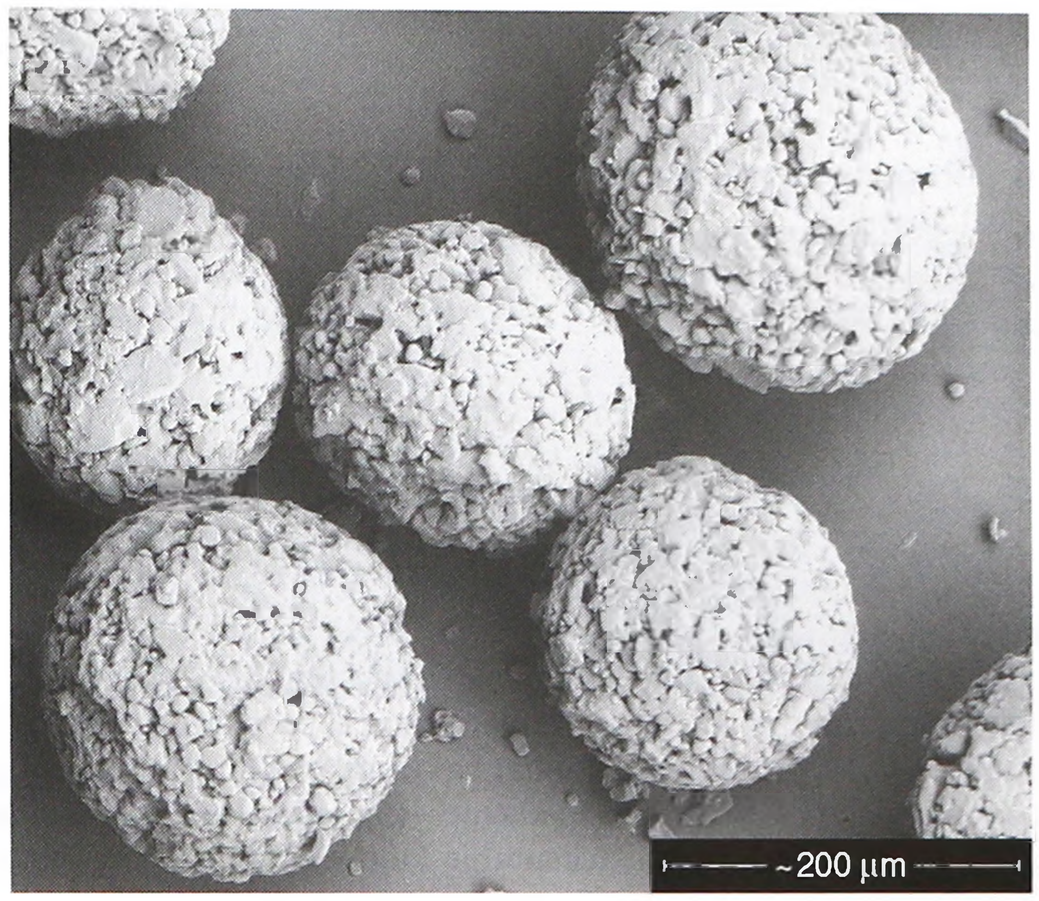
Both lactose monohydrate and corn (maize) starch are listed as separate monographs in the JP, PhEur, and USP–NF, but the combination is not currently listed. The pharmacopeial specifications for lactose monohydrate and corn starch have been harmonized for JP, PhEur, and USP–NF.

See Lactose Monohydrate, and Starch. *See also* Section 18.

10 Typical Properties

Angle of repose ≤29° for *StarLac*
Density (bulk) 0.57 g/cm^3 for *StarLac*
Density (tapped) 0.68 g/cm^3 for *StarLac*

SEM 1: Excipient: *StarLac*; manufacturer: Meggle/Roquette; magnification: 200×; voltage: 2 kV.



SEM 2: Excipient: *StarLac*; manufacturer: Meggle/Roquette; magnification: 350×; voltage: 5 kV.