Lactose Monohydrate and Microcrystalline Cellulose, Coprocessed

1 Nonproprietary Names

None adopted.

2 Synonyms

MicroceLac 100.

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

Tablet and capsule diluent; direct compression excipient.

7 Applications in Pharmaceutical Formulation or Technology

Coprocessed lactose monohydrate and microcrystalline cellulose can be used in tablets for direct compression, as a capsule diluent, and as a filler-binder in roller compaction processes.[1]

8 Description

Coprocessed lactose monohydrate and microcrystalline cellulose occurs as a white to nearly white odorless powder comprising of 73–77% lactose monohydrate and 23–27% microcrystalline cellulose in an integrated particle, which cannot be achieved via simple blending. It is a free-flowing powder due to its spherical structure and typical median particle size.

9 Pharmacopeial Specifications

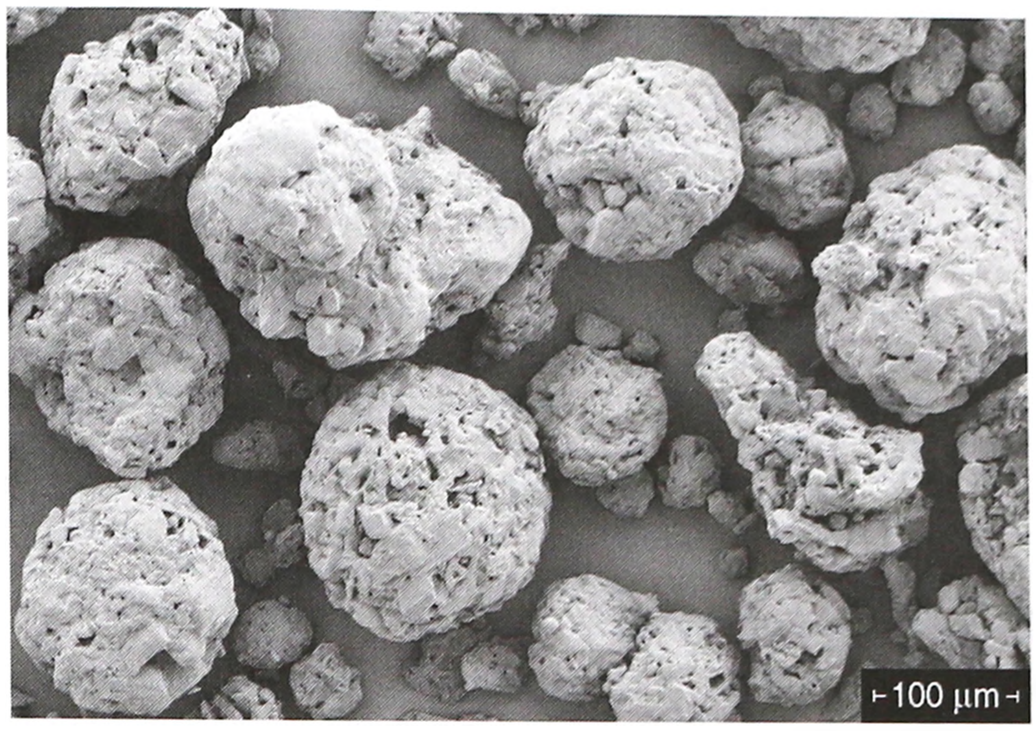
Both lactose monohydrate and microcrystalline cellulose are listed as separate monographs in the JP, PhEur, and USP–NF, but the combination is not currently listed. The pharmacopeial specifications for both lactose monohydrate and microcrystalline cellulose have undergone harmonization for many attributes for JP, PhEur, and USP-NF.

See Lactose Monohydrate, and Cellulose, Microcrystalline. *See also* Section 18.

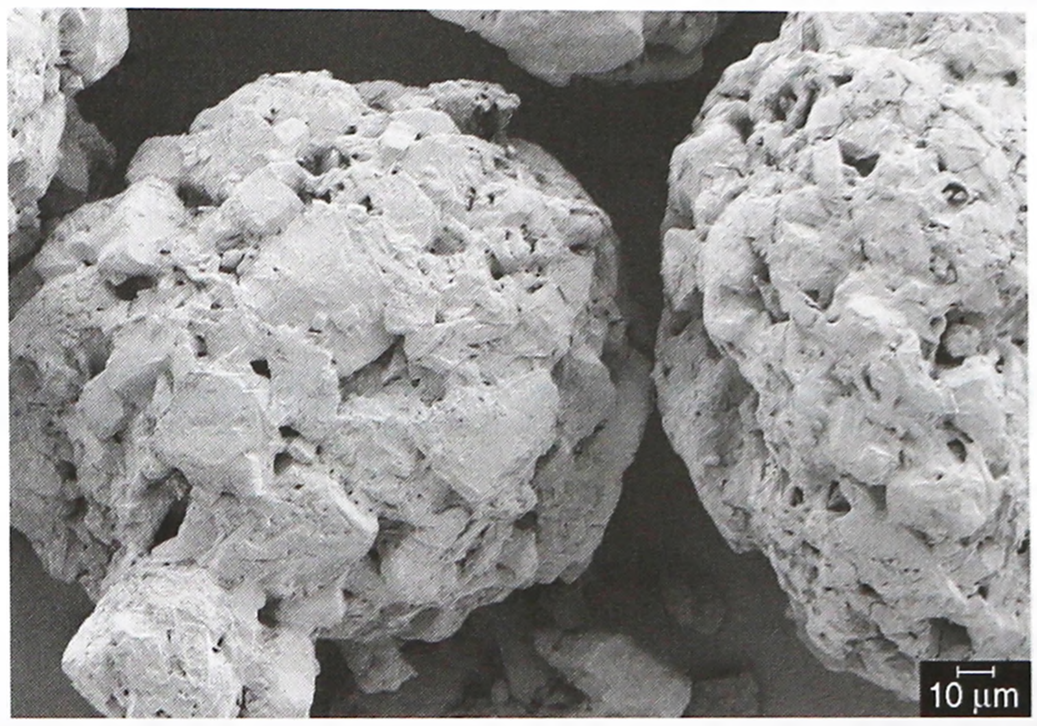
10 Typical Properties

Acidity/alkalinity pH = 4.0–7.0 for *MicroceLac 100*
Angle of repose 34° for *MicroceLac 100*
Density (bulk) 0.5 g/cm^3 for *MicroceLac 100*
Density (tapped) 0.61 g/cm^3 for *MicroceLac 100*
Hausner ratio 1.16 for *MicroceLac 100*
Heavy metals ≤5 ppm for *MicroceLac 100*
Loss on drying ≤1.5% for *MicroceLac 100*
Microbial content Total viable aerobic count ≤100 cfu/g, molds ≤10 cfu/g, yeasts ≤10 cfu/g (*Escherichia coli* and *Salmonella* species absent) for *MicroceLac 100.*
Particle size distribution ≤15% <32 µm, 45–70% <160 µm, ≥90% <250 µm for *MicroceLac 100.*
Solubility Partially soluble in water for *MicroceLac 100*

SEM 1: Excipient: *MicroceLac 100*; manufacturer: Meggle; magnification: 200×; voltage: 3 kV.



SEM 2: Excipient: *MicroceLac 100*; manufacturer: Meggle; magnification: 500×; voltage: 3 kV.



Sulfated ash ≤0.1% for *MicroceLac 100*
Water content 4–6% for *MicroceLac 100*

11 Stability and Storage Conditions

Store at room temperature in well-closed containers under dry and odor-free conditions.

12 Incompatibilities

See Lactose Monohydrate, and Cellulose, Microcrystalline.

13 Method of Manufacture

Coprocessed lactose monohydrate and microcrystalline cellulose is prepared by co-spray-drying a mixture of the two ingredients.

14 Safety

See Lactose Monohydrate, and Cellulose, Microcrystalline.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.