Lactose Monohydrate and Powdered Cellulose, Coprocessed

1 Nonproprietary Names

None adopted.

2 Synonyms

Cellactose 80.

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.

7 Applications in Pharmaceutical Formulation or Technology

Coprocessed lactose monohydrate and powdered cellulose can be used for tablet manufacture by direct compression to improve compressibility and mouth-feel.[1] Coprocessed lactose monohydrate and powdered cellulose has also been investigated for roller compaction processes.[2]

8 Description

Coprocessed lactose monohydrate and powdered cellulose occurs as a white to nearly white odorless powder comprising of 73–77% lactose monohydrate and 23–27% cellulose powder 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

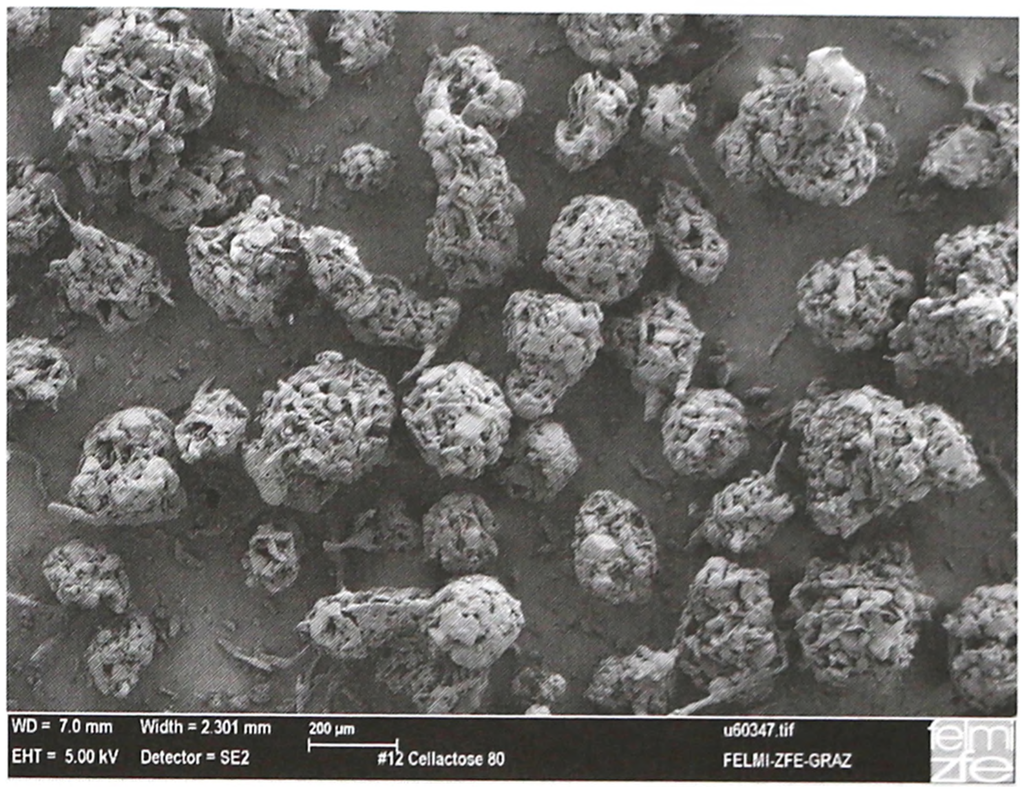
Both lactose monohydrate and powdered cellulose are listed as separate monographs in the JP, PhEur, and USP–NF, but the combination is not currently listed. The pharmacopeial specifications for both lactose monohydrate and powdered cellulose have undergone harmonization for many attributes for JP, PhEur,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

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

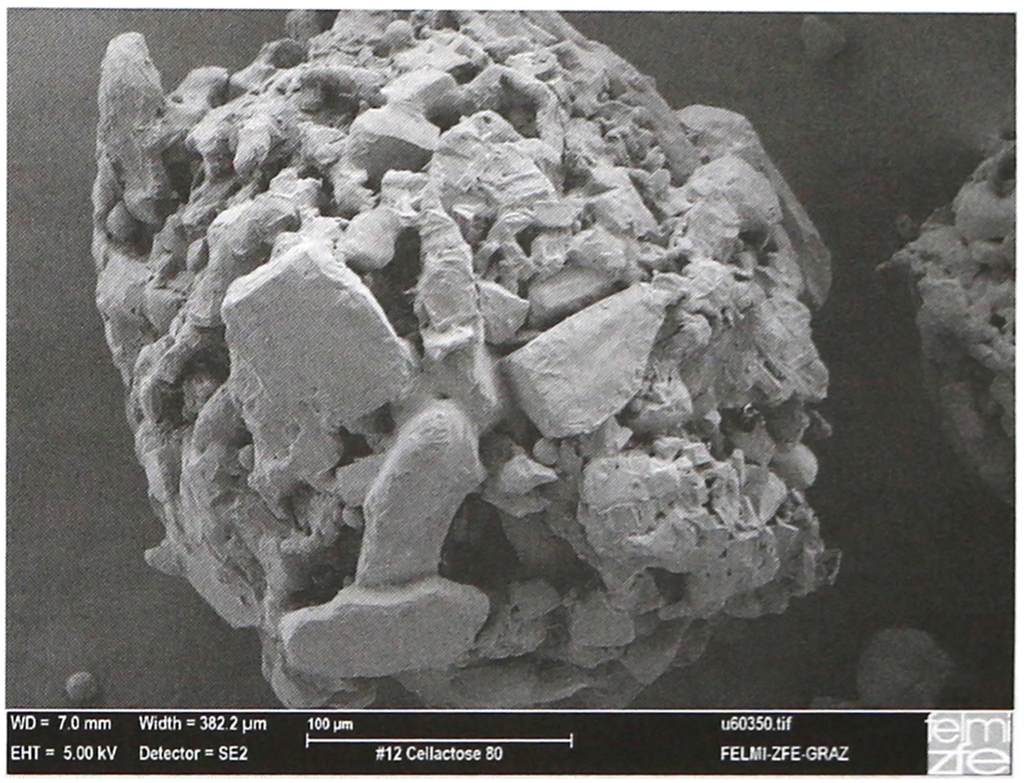
10 Typical Properties

Acidity/alkalinity pH = 4.0–7.0 for *Cellactose 80*
Angle of repose 32–35° for *Cellactose 80*
Density (bulk) 0.38 g/cm^3 for *Cellactose 80*
Density (tapped) 0.5 g/cm^3 for *Cellactose 80*
Hausner ratio 1.24 for *Cellactose 80*
Heavy metals ≤5 ppm for *Cellactose 80*
Loss on drying ≤3.5% for *Cellactose 80*
Microbial content Total viable aerobic count ≤100 cfu/g, molds ≤10 cfu/g, yeast ≤10 cfu/g (*Escherichia coli* and *Salmonella* species absent) for *Cellactose 80.*
Particle size distribution ≤20% <32 µm, 35–65% <160 µm, ≥80% <250 µm for *Cellactose 80.*
Sulfated ash ≤0.2% for *Cellactose 80*
Solubility Partially soluble in water for *Cellactose 80*
Water content 4–7% for *Cellactose 80*

SEM 1: Excipient: *Cellactose 80*; manufacturer: Meggle; magnification: 50×; voltage: 5.0 kV.



SEM 2: Excipient: *Cellactose 80*; manufacturer: Meggle; magnification: 300×; voltage: 5.0 kV.



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, Powdered.

13 Method of Manufacture

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