Lactose, Spray-Dried

1 Nonproprietary Names

None adopted.

2 Synonyms

FlowLac 90; *FlowLac 100*; *Lactopress Spray-Dried*; *Lactopress Spray-Dried 250*; *Lactopress Spray-Dried 260*; *Foremost Lactose 315*; *Foremost Lactose 316 Fast Flo*; *SuperTab 11SD*; *SuperTab 14SD*.

3 Chemical Name and CAS Registry Number

Spray-dried lactose is a mixture of amorphous and crystalline lactose monohydrate, O-β-D-galactopyranosyl-(1→4)-α-D-glucopyranose monohydrate.

CAS numbers for lactose monohydrate include [5989-81-1] (lactose monohydrate); [10039-26-6] (lactose monohydrate, cyclic); [64044-51-5] (lactose monohydrate, open form).

4 Empirical Formula and Molecular Weight

$C_{12}H_{22}O_{11}$ 342.30 (for amorphous)
$C_{12}H_{22}O_{11}\cdot H_2O$ 360.31 (for monohydrate)

5 Structural Formula

See Lactose, Anhydrous and Lactose Monohydrate.

6 Functional Category

Direct compression excipient; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Spray-dried lactose is widely used as a binder, filler-binder, and flow aid in direct compression tablet manufacture.

See also Lactose Monohydrate; Lactose, Anhydrous.

8 Description

Spray-dried lactose occurs as white to nearly white crystalline particles or powder. It is odorless and slightly sweet-tasting. Spray-dried, direct-compression lactose grades are generally composed of 80–90% crystalline α-lactose monohydrate, which is brittle in nature, and 10–20% amorphous lactose, which is plastically deforming.[1]

9 Pharmacopeial Specifications

See Section 18. *See also* Lactose Monohydrate.

10 Typical Properties

Angle of repose 29° for *FlowLac 90*.
Density bulk *see* Table I.
Loss on drying ≤1.0% for *FlowLac 90*
Particle size distribution *see* Table II.
Spectroscopy

IR spectrum *see* Figure 1.

Raman spectrum *see* Figure 2.

Water content *see* Table I.

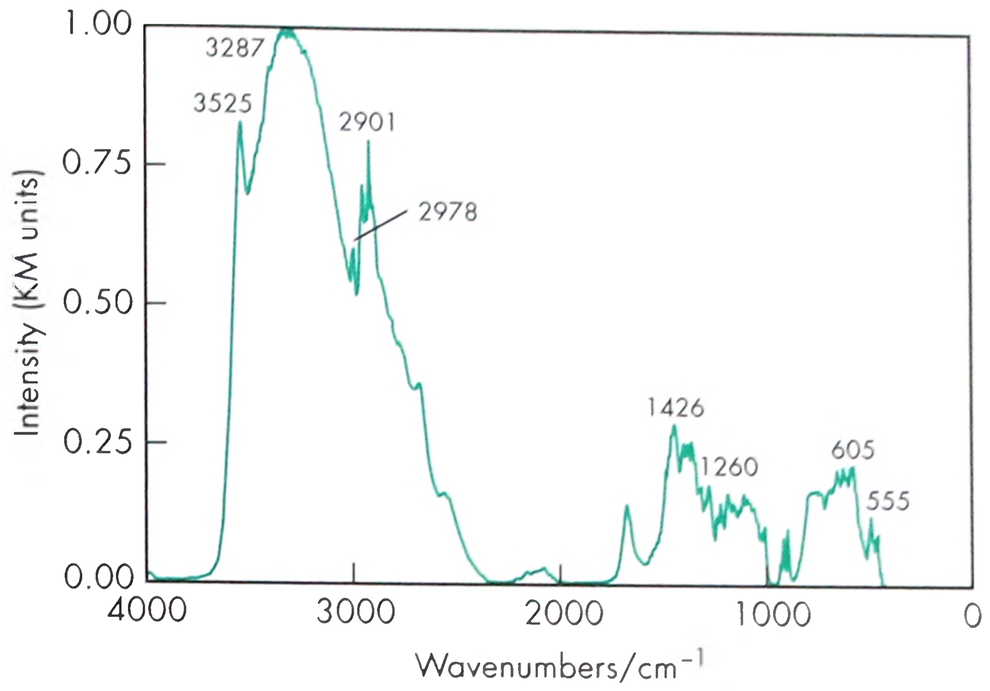

Figure 1: Infrared spectrum of spray-dried lactose measured by diffuse reflectance. Adapted with permission of Informa Healthcare.

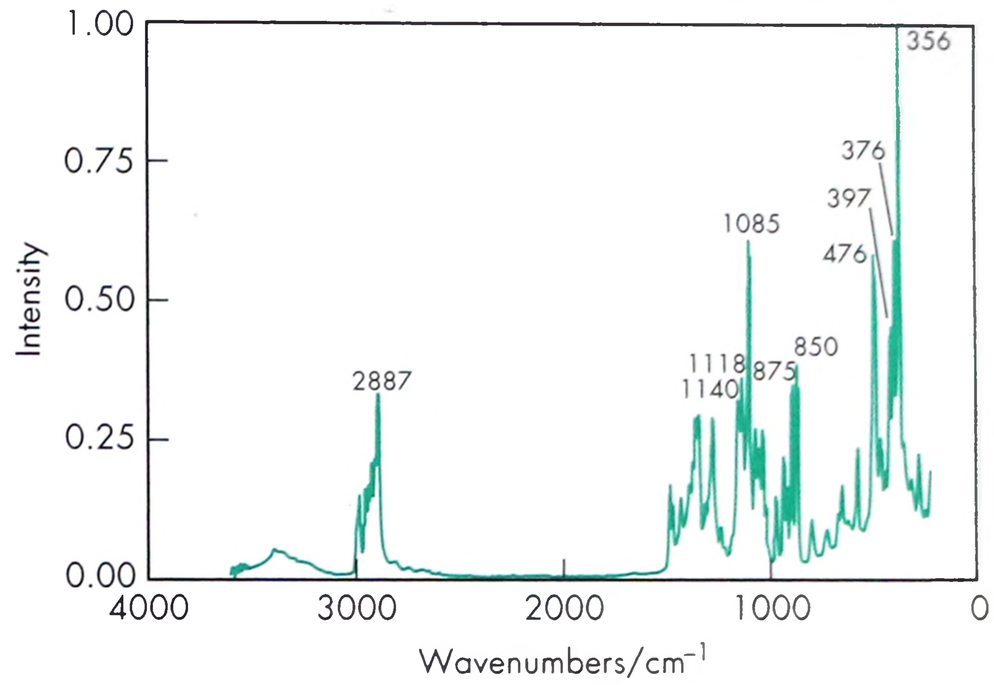

Figure 2: Raman spectrum of spray-dried lactose measured in the 180° reflectance mode. Adapted with permission of Informa Healthcare.

Table I: Typical physical properties of selected commercially available spray-dried lactose.

Supplier/grade	Density (bulk) (g/cm³)	Density (tapped) (g/cm³)
DFE Pharma		
SuperTab 11SD	0.60	0.71
SuperTab 14SD	0.62	0.72
Meggle GmbH		
FlowLac 90	0.57	0.67
FlowLac 100	0.62	0.71

11 Stability and Storage Conditions

Spray-dried lactose should be stored in a well-closed container in a cool, dry, odor-free place.

12 Incompatibilities

Lactose is a reducing sugar. The amorphous lactose, which is the most reactive form of lactose present in spray-dried lactose, will