

# Lactose Monohydrate and Povidone, Coprocessed

## 1 Nonproprietary Names

None adopted.

## 2 Synonyms

Ludipress LCE.

## 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 povidone can be used to formulate chewable tablets, lozenges, effervescent tablets, and controlled-release tablets by direct compression.<sup>(1,2)</sup> It is suitable for low-dose drugs.<sup>(3)</sup>

## 8 Description

Coprocessed lactose monohydrate and povidone occurs as white free-flowing granules, odorless with a neutral taste, containing  $96.5\% \pm 1.8\%$  lactose monohydrate and  $3.5\% \pm 0.5\%$  povidone K30.

## 9 Pharmacopeial Specifications

Both lactose monohydrate and povidone 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 povidone have undergone harmonization for many attributes for JP, PhEur, and USP-NF.

See Lactose Monohydrate, and Povidone. See also Section 18.

## 10 Typical Properties

**Angle of repose**  $29.5^\circ$  for Ludipress LCE

**Density (bulk)**  $0.56 \pm 0.6 \text{ g/cm}^3$  for Ludipress LCE

**Hausner ratio**  $1.20 \pm 0.10$  for Ludipress LCE

**Heavy metals**  $\leq 10 \text{ ppm}$  for Ludipress LCE

**Loss on drying**  $5.75\%$  for Ludipress LCE

**Microbial content** Mesophilic aerobes  $\leq 1000 \text{ cfu/g}$ , yeasts and fungi  $\leq 100 \text{ cfu/g}$  (*Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella* species absent), other Enterobacteriaceae  $\leq 100 \text{ cfu/g}$  for Ludipress LCE.

**Particle size distribution**  $\leq 20\%$   $< 63 \mu\text{m}$ ,  $40\text{--}65\%$   $< 200 \mu\text{m}$ ,  $\leq 20\%$   $< 400 \mu\text{m}$  for Ludipress LCE.

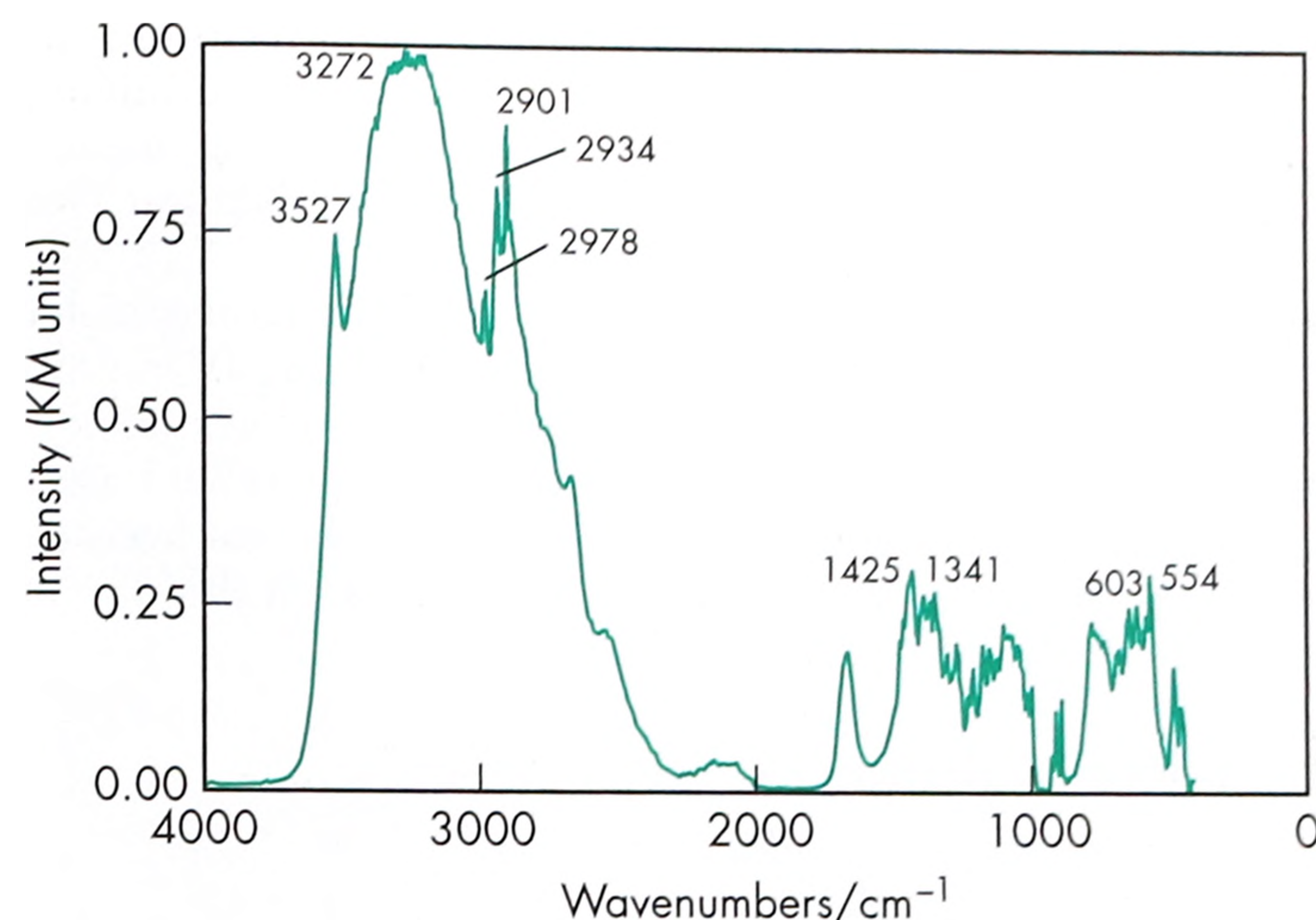
**Solubility** Soluble in water for Ludipress LCE

### Spectroscopy

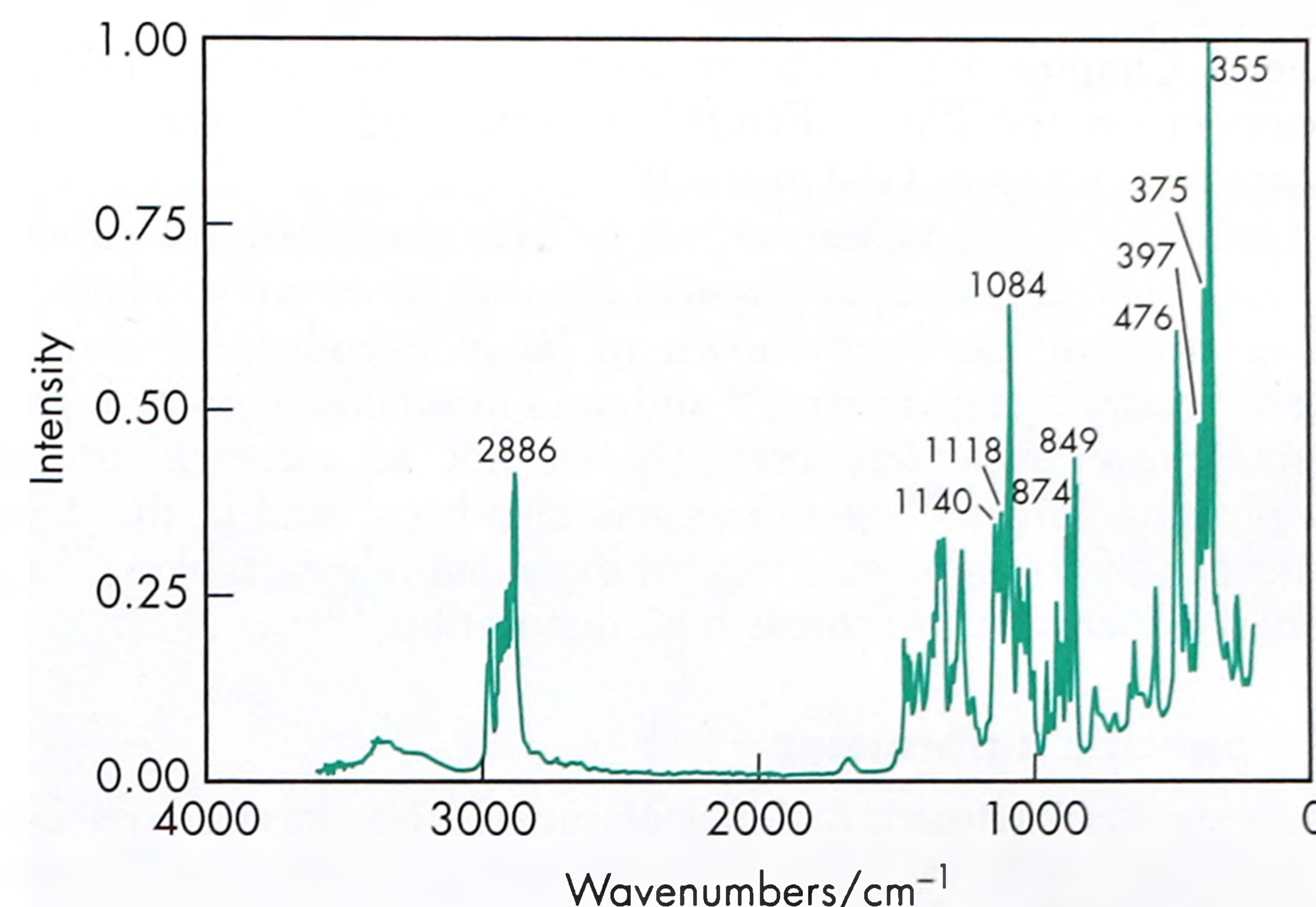
IR spectrum see Figure 1.

Raman spectrum see Figure 2.

**Water content**  $\leq 6.0\%$  for Ludipress LCE



**Figure 1:** Infrared spectrum of coprocessed lactose monohydrate and povidone measured by diffuse reflectance. Adapted with permission of Informa Healthcare.



**Figure 2:** Raman spectrum of coprocessed lactose monohydrate and povidone measured in the  $180^\circ$  reflectance mode. Adapted with permission of Informa Healthcare.

## 11 Stability and Storage Conditions

Store at room temperature in tightly closed containers.

## 12 Incompatibilities

See Lactose Monohydrate, and Povidone.

## 13 Method of Manufacture

Coprocessed lactose monohydrate and povidone is manufactured by a proprietary agglomeration process.

## 14 Safety

See Lactose Monohydrate, and Povidone.

## 15 Handling Precautions

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