


## Hilmar™ 5320 Lactose USP/NF/EP/JP 200#

Hilmar™ 5320 is a crystalline alpha monohydrate lactose manufactured using a double crystallization, filtration and purification process to meet strict international pharmaceutical excipient standards including USP, NF, EP, JP and IP. Its exceptional quality and purity allows its use in a wide range of pharmaceutical preparations. This milled 200 mesh crystalline grade is most suited to wet granulation tablet manufacture.

### FEATURES / BENEFITS

- Superior Consistency, Purity and Clarity
- Meets Stringent Color Specifications
- Natural Carbohydrate
- Kosher  and Halal Approved
- EU Approved
- FDA Approved

### APPLICATIONS

- Filler or diluent for tablets, capsules, sachets, and a wide variety of other pharmaceutical preparations
- Filler or diluent for certain veterinary preparations and mixes
- Filler or diluent for nutraceuticals and other health foods
- Filler or diluent in certain homeopathic preparations
- Ingredient for culture media
- Infant formula

### PHYSICAL CHARACTERISTICS

Hilmar™ Pharmaceutical Lactose is a free flowing, non-hygroscopic powder. A 10% solution is clear and colorless.

Particle Size	Typical %
USS 100# (passing)	95 ± 5
USS 200# (passing)	80 ± 5
USS 325# (passing)	50 ± 5

Bulk Density	Typical Range
Poured Density	0.5 – 0.7 g/ml

### QUALITY CONTROL SPECIFICATIONS

Composition	Specification
Lactose Content (%)	99.7 min
Loss on Drying (%)	0.5 max
Protein & Impurities (220nm)	0.25AU max
Protein & Impurities (280nm)	0.07AU max
Residue on Ignition (%)	0.1 max
Acidity (0.1N NaOH)	0.4 ml max
Heavy Metals (µg/g)	5.0 max
Total Water Content (%)	4.5 - 5.5
Specific Rotation	+ 54.5° to + 55.9°

Microbiology	Specification
APC (cfu/g)	100 max
<i>E. coli</i> (cfu/10g)	Negative
<i>Salmonella sp.</i> (25g)	Negative
Yeast (cfu/g)	10 max
Mold (cfu/g)	10 max

### PACKAGING

25 kg heat-sealed, multi-wall kraft bag with inner polyethylene bag liner. Forty bags per pallet.

### STORAGE / SHELF LIFE

Shelf life is three years from the date of manufacture. Recommended storage is less than 25° C and 75% relative humidity. Store away from aromatic materials.

### RECOMMENDED LABEL

Lactose Monohydrate 200# USP/EP/JP/NF

### ORDERING INFORMATION

BAG SIZE	PART CODE	FOB
25 kg	350005	Hilmar, CA

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