



TECHNICAL INFORMATION

Kerry Inc.
3330 Millington Road Beloit, WI 53511 USA
Tel: 608.299.5100
www.kerry.com

Technical Data Sheet

PRODUCT DETAILS

Part Number	All Codes
SAP Code	
Product Name	Sheffield™ Monohydrate 312
Product Description	Lactose is a disaccharide obtained from the whey fraction of milk consisting of one glucose and one galactose moiety. Sheffield™ Monohydrate 312 meets all requirements of the current National Formulary, the European Pharmacopeia, and the Japanese Pharmacopeia. All ingredients are certified rennet free.

INGREDIENT DECLARATION

Lactose Monohydrate

Kosher, Dairy

(Contains Milk)

USAGE DETAILS

Sheffield™ Monohydrate 312 is recommended as an excipient, filler, diluent, and bulking agent in a wide variety of pharmaceutical tablets, capsules, powders, and other preparations. It also has applications as a nutrient and multifunctional ingredient in infant formulas, geriatric, dietetic and health foods and may be used as an ingredient in culture media.



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KEY PERFORMANCE PARAMETERS

Analysis	Specification	Test Method
Absorbance at 400nm	< 0.04	NF, Clarity & Color of Solution
Visual Exam	Clear/Colorless	NF, Clarity & Color of Solution
Acid Value	< 0.4	NF, Acidity or Alkalinity
Visual Exam	Colorless	NF, Acidity or Alkalinity
Residue on Ignition	< 0.1	USP <281>
Identification A	Meets Standard	USP <197K>
Identification B	Meets Standard	USP <201>
Water	4.5 - 5.5	USP <921>, Method I
Loss On Drying	< 0.50	USP <731>
Absorbance 210 TO 220 nm	< 0.25	Protein & Light Absorbing Impurities
Absorbance 270 TO 300 nm	< 0.07	Protein & Light Absorbing Impurities
Bulk Density	> 0.45	USP <616>
Tapped Density	> 0.70	USP <616>
Percent On 140 Mesh	< 1.0	USP <786>, ROTAP
Percent On 200 Mesh	< 6.0	USP <786>, ROTAP
Specific Rotation	54.4 - 55.9	USP <781S>
Appearance of Solution	Pass	EP, Visual Inspection

PHYSICAL DESCRIPTION

Form: White, crystalline powder

MICROBIOLOGICAL DATA

Analysis	Specification	Test Method
E. Coli	Absent	USP <62>
Enterobacteriaceae	Absent	USP <62>
Pseudomonas Aeruginosa	Negative per 10g	Difco 11th Ed.
Staphylococcus aureus	Negative per 10g	USP
Salmonella	Absent	JP <4.05>
Aerobic Plate Count	< 100 cfu/g	USP <61>
Yeasts & Moulds	< 50 cfu/g	USP <61>



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SHELF-LIFE & STORAGE

365 days unopened Avoid excessive heat. Protect from moisture. Do not freeze.

PACKAGING

Packaging Type: Multilayer Paper Bag, Fiber Drum with Polyethylene Liner

RECOMMENDED ALLERGEN DATA FOR LABELING PURPOSES

Is the product FREE FROM...?	Yes = Absent, No = Present
Dairy/Dairy Derivatives	NO
Egg/Egg Derivatives	YES
Soy/Soy Derivatives	YES
Wheat/Wheat Derivatives	YES
Peanuts/Peanut Derivatives	YES
Treenut/Treenut Derivatives	YES
Fish/Fish Derivatives	YES
Shellfish/Shellfish Derivatives	YES
Gluten/Gluten Derivatives	YES

LEGISLATION & WARRANTY STATEMENT

The product will be manufactured in accordance with all current relevant US legislation. The information stated is given in good faith and is based upon the product formulation and the data provided by our raw material suppliers.

All reasonable precautions that could be expected of a responsible manufacturer have been taken, however no absolute guarantees can be given that trace / carry over residues will be totally absent.

CONFIDENTIALITY

This specification and the information contained within it remains the property of this company and must not be disclosed to any third party without the prior written permission of the company.