



Lactose Standard

Product Definition

Lactose (Milk Sugar) is a white to creamy white crystalline product, possessing a mildly sweet taste. It may be anhydrous; contain one molecule of water of hydration; or may be a mixture of both forms. It is manufactured from whey or permeate by evaporating, crystallizing, refining and then drying the lactose crystals. Lactose for human consumption complies with all provisions of the U.S. Federal Food, Drug, and Cosmetic Act.

Composition

Parameter	Units of Measure	Limits		
		Industrial / Fermentation Grade Lactose	Edible (Food Grade) Lactose	Refined Edible Grade Lactose
Lactose	%, dry basis	98.0 minimum	99.0 minimum	99.50 minimum
Protein	%, dry basis	1.0 maximum	0.30 maximum	0.15 maximum
Ash (phosphated)	%, dry basis	0.45 maximum	0.30 maximum	0.20 maximum
Total moisture ¹	%, as-is basis	6.0 maximum	6.0 maximum	6.0 maximum

1 - Includes water of crystallization.

Mesh Size

Edible Lactose is often sized through a combination of pulverizing and/or screening steps to yield a suitable particle size distribution. Mesh size requirements are variable and are determined by the individual manufacturer and/or customer.

Product	Sieve Sizes (Mesh)	% Pass Through
40 mesh	40	80 minimum
100 mesh	100	80 minimum
200 mesh	200	80 minimum

Other Characteristics

Physico-chemical Properties		
Parameter	Units of Measure	Limits
Scorched particles	mg/25g	15.0 maximum
pH	-	4.5 – 7.5
Color	visual	white to pale yellow

Physico-chemical Properties		
Parameter	Units of Measure	Limits
Flavor	sensory	slightly sweet; free from offensive flavors
Physical appearance	visual	free of lumps that do not break up under slight pressure; free of foreign material

Microbiological Analysis		
Parameter	Units of Measure	Limits
Standard plate count	CFU/g	2,500 maximum
Coliforms ²	CFU/g	10 maximum
<i>Enterobacteriaceae</i> ²	CFU/g	10 maximum
<i>Salmonella</i>	CFU/25g	not detected
<i>Staphylococcus</i> (coagulase positive)	CFU/g	not detected ³
<i>Listeria</i> genus	CFU/g	not detected

- 2- The food industry is trending toward *Enterobacteriaceae* ("EB") as the most commonly used category of indicator organisms for gauging general process sanitation. For compliance with this Standard, either coliforms and/or EB shall be utilized, at the discretion of the manufacturer.
- 3- Where the effective limit of quantitation for the test is 10 CFU/g (such as when a dilution factor of 10 is applied) then the test result must be not detected in order to comply with this Standard. Where the testing method is capable of quantifying microbial counts below 10 CFU/g, then a compliant result must be a value less than 10 CFU/g.

Methods of Analysis

Parameter	Reference Method
Lactose	ISO 22662 / IDF 198
Protein	AOAC 991.20 (N x 6.38)
Moisture	ISO 5537 / IDF 26
Ash	AOAC 942.05
pH	USDA
Microbiological tests	FDA BAM

Product Labeling

Recommended identification: Lactose, or Milk Sugar

Typical Applications

Lactose applications include: infant foods, chemicals/pharmaceuticals, dairy products, prepared dry mixes, bakery products, soft drinks, special dietary foods, confections, and others.

See the separate ADPI standard for [Dry Blend Infant Formula \(IF\) Grade Lactose](#) for additional requirements in that specific application.

Typical Storage & Shipping

Product should be stored, shipped, and utilized according to the manufacturer's established recommendations. As guidance, product should be stored and shipped in a cool, dry environment with temperature below 80°F and relative humidity below 65%. Stocks should be rotated and utilized in accordance with the manufacturer's established date of expiration or retest.

Typical Packaging

Multiwall kraft bags with polyolefin inner liner, or other suitable closed containers (e.g., totes) are typical.

Revision History

This Standard is a legacy document and has been assigned prior version numbers on an *ex post facto* basis, according to its documented history of modifications, in order to comply with our new document control features and format. Full revision history is on file at ADPI and is available for query via info@adpi.org or by directly contacting the Vice President of Technical Services.

Current version details:

Current Version	Effective Date	Notes
4.0	06/07/2023	Migrated this Standard to the new modernized format as authorized by the ADPI Standards Committee. No previously established test parameters or limits were materially altered by this update, but this revision did require a footnote to clarify the restatement of the limit for coagulase positive <i>Staphylococcus</i> .