METAPHARMACEUTICAL

TECHNICAL DATA SHEET

1172-TDS-ENG-2025

LACTOSA MONOHIDRATO 200 MESH (EUR. PH.)		
DESCRIPTION DCI: LACTOSE	DESCRIPTION DOE: LACTOSA	
CAS Nº: 5989-81-1	EC Nº: 611-913-4	AEMPS CODE: ---
MOL. WEIGHT: 360,30	MOL. FORMULA: C12H22O11·H2O	ARTICLE CODE: 1172

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Freely soluble in water, practically insoluble in ethanol (96 %)
Identification A	Complies
Identification D	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7
Acidity or alkalinity	=< 0.4 mL of 0.1 M NaOH
Specific optical rotation	+54.4 / +55.9
Absorbance	
Maximum at 400 nm	=< 0.04
Maximum at 210-220 nm	=< 0.25
Maximum at 270-300 nm	=< 0.07
Water	4.5 - 5.5 %
Sulfated ash	=< 0.1 %
Microbiological control	
TAMC	100 CFU/g
E. Coli	Absence/1g

COMPLIES WITH

European Pharmacopoeia 11.5

STORAGE

Keep tightly closed in a cool, dry place away from heat, flames, sparks and other sources of ignition.

REMARKS

Lactose Monohydrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses
LACTOSE is widely used in the pharmaceutical industry in the manufacture of capsules and tablets (diluent), powders (to give volume), and as a vehicle for drugs in dry powder inhalers. Because it is not inert, it is not free of risks. Absorbs the

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869

TECHNICAL DATA SHEET

1172-TDS-ENG-2025

LACTOSA MONOHIDRATO 200 MESH (EUR. PH.)		
DESCRIPTION DCI: LACTOSE	DESCRIPTION DOE: LACTOSA	
CAS Nº: 5989-81-1	EC Nº: 611-913-4	AEMPS CODE: ---
MOL. WEIGHT: 360,30	MOL. FORMULA: C12H22O11·H2O	ARTICLE CODE: 1172

moisture of the hygroscopic active principles and is useful for water-insoluble active principles (since it makes the mixture more hydrophilic), but in a basic medium it is oxidized and gives yellowing by-products.
LACTOSE is also a mild laxative and diuretic.
It is also used as a nutrient in the preparation of modified milk for children and convalescents to adjust its carbohydrate content, although it is advisable to use it in moderation since it can produce a laxative effect and too acidic stools.

Side effects
Intolerance to LACTOSE when there is lactase deficiency. In patients with deficiency of this enzyme, the ingestion of LACTOSA leads to a clinical picture characterized by diarrhea, abdominal pain, bloating and flatulence.
These symptoms can also occur in patients without this deficiency, but who have ingested excessive amounts of LACTOSE.

Contraindications
Galactosemia Glucose malabsorption syndrome LACTOSE. Lactase deficiency.

Precautions
Being a nutritious carbohydrate, it should be used in the least amount possible or avoid its use in antidiabetic pharmaceutical forms.

Incompatibilities
Amino acids, amphetamines, and alkaline substances such as aminophylline, nicotinamide, hydralazine, etc ... that oxidize LACTOSE and turn it yellowish (Moore's reaction). It explodes with oxidizing products such as chlorates.

Other observations
Mandatory declaration excipient. It must be included in the information given to the patient. NO Suitable Food use.

Compounding example

Tartaric acid - **50 g**
Magnesium oxide - **60 g**
Active carbon - **150 g**
LACTOSE - **40 g**

Modus operandi: weigh the powders from lowest to highest weight, mixing them until total interposition and homogeneity.

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869