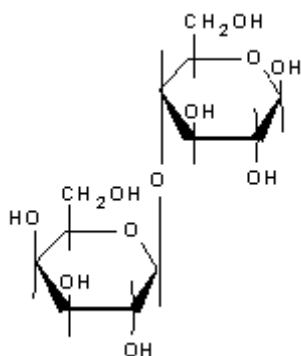
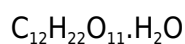
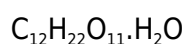




PRODUCT CODE: 141375

D(+)-Lactose 1-hydrate (USP-NF, BP, Ph. Eur.) pure, pharma grade



M.= 360,32

CAS [10039-26-6]

EINECS 200-559-2

TARIC 1702 19 00 00

SYNONYMS: 4-O-b-D-Galactopyranosyl-D-Glucose, Milk sugar

PHYSICAL DATA: Small crystals, White, Soluble in water 216 g/l at 20 °C M.P.: 202 °C • pH(50g/l)4 - 6 •

BIBLIOGRAPHY: Merck Index **13**, 5.358 Beilstein **17 V**, **7/196** • BRN 3768231 • ACS **XI** • BP.**2020** • USP **-NF 37**
• Ph. Eur. **9.0** (2017) 5.7, 5042 **10.0** (2020) 5.7, 5042 6.3, 6.5 • F.C.C **10 11** •

HAZARDOUS: RTECS: OD 9625000 •

SPECIFICATIONS:

Identity :

Identity according to Pharmacopoeias:

Specific rotation $[\alpha]_{20/D} c = 10$ (in H₂O)

passes test

+54,4 - +55,9°

Maximum limit of impurities

ABS	
at λ 270-300 nm 1% sol. in H ₂ O	0,07
at λ 400 nm 10% sol. in H ₂ O	0,04
at λ 210-220 nm 1% sol. in H ₂ O	0,25
Appearance of solution	passes test
Acidity or alkalinity	passes test
Insoluble matter in H ₂ O	passes test
Loss on drying at 80°C	0,5%
Residue on ignition (as SO ₄)	0,1 %
Chloride (Cl)	0,01%
Sulfate (SO ₄)	0,02%
Residual solvents (Ph.Eur/USP)	passes test
Water (H ₂ O)	4,5-5,5 %
Contamination Microbial limits:	
Total aerobic microbial count (TAMC)	100 cfu /g
Yeasts and molds	50 cfu/g
Escherichia coli	negative
Salmonella	negative
Heavy metals (as Pb)	0,0005%

Elemental impurities (ICH Q3D):

Class 1

Cd	0,5 ppm
Pb	5 ppm
As	1 ppm
Hg	1,5 ppm

Class 2A

Co	5 ppm
V	10 ppm
Ni	20 ppm

Class 2B

Tl	5 ppm
Au	10 ppm
Pd	10 ppm
Ir	10 ppm
Os	10 ppm
Rh	10 ppm
Ru	10 ppm
Se	15 ppm
Ag	15 ppm
Pt	10 ppm

Class 3

Li	55 ppm
Sb	120 ppm
Ba	140 ppm
Mo	25 ppm
Cu	250 ppm
Sn	600 ppm
Cr	25 ppm

Product obtained from animal milk with collection in the same conditions that the

milk obtained for human consumption.

Ed.: 7 . Vig.: 20.07.2017 .

Prod.: 141375