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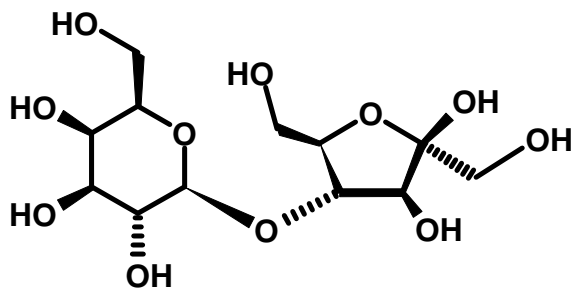
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Product Specifications

Lactulose Liquid (660 g/L)

CAS 4618-18-2

Structure:



Mol. Formula
Source

$C_{12}H_{22}O_{11}$
Synthetic

Mol. Wt.

242.30

Test

Specification

Identity

Reaction with cupri-tartaric solution	Red precipitate is formed (EP)
Reaction with ammonia	Red color develops (EP)
Appearance	Clear, Colorless to pale-brown to pale-yellow, viscous liquid. It may be a supersaturated solution or may contain crystals that disappear on heating.

Assay (hplc)

95% to 105% (EP)

Related Substances (hplc)

Impurity B	≤ 15%	(EP)
Impurity A	≤ 10%	(EP)
Impurity C	≤ 10%	(EP)
Impurity E	≤ 4%	(EP)
Impurity D	≤ 1%	(EP)
Unknown impurity 1 at RRT 0.14	≤ 1.6%	(EP)
Unknown impurity 2 at RRT 0.76	≤ 0.5%	(EP)
Unknown impurity 3 at RRT 0.83	≤ 0.7%	(EP)
Unknown impurity 4 at RRT 0.61	≤ 0.3%	(EP)

- cont'd -

- cont'd -

<i>Test</i>	<i>Specification</i>
Any other impurity	≤ 0.05% (EP)
Total Impurities	≤ 15.4% (EP)
Density	1.270 - 1.370 g/mL (EP <2.2.5>)
Residual Solvents (MeOH)	≤ 30 ppm (EP)
Sulfites	≤ 30 ppm (EP)
Boron (B)	≤ 5 ppm (EP)
Lead (Pb)	≤ 0.5 ppm (EP)
Sulfated Ash	≤ 0.2% (EP)
<u>Microbiological Specification</u>	
Total Aerobic plate count	≤ 100 cfu/g
<i>E. Coli</i>	absent
Mold and Yeast	≤ 10 cfu/g

Storage: Maintain in cool, dry containment.