



LACTULOSE CONCENTRATE 66.0% w/v USP/BP/Ph.Eur

Product description:

Lactulose concentrate is a colourless to brownish-yellow, clear or not more than slightly opalescent solution. Miscible with water. Lactulose is odourless, with a sweet taste. The product complies with BP/USP/Ph.Eur.

SPECIFICATION:

TEST	SPECIFICATION:	
Characteristics	Ph.Eur/BP	A clear, viscous liquid, colourless to pale brownish-yellow, miscible with water. It may be a supersaturated solution or may contain crystals which disappear on heating. A 10% v/v solution is laevorotatory.
	USP	Colourless or amber syrupy liquid which may exhibit some precipitation and darkening upon standing. Miscible with water.
Identification	USP (A)	The retention time of the of the mayor peak in the chromatogram of the assay preparation corresponds to that of the standard preparation.
	Ph.Eur/BP (B)	
Identification	USP (B)	A red precipitate of cuprous oxide is produced.
	Ph.Eur/BP (C)	
Identification	Ph.Eur/BP (D)	A red colour develops.
Appearance of solution		Clear and not more intensively coloured than the reference solution BY5.
Sulphite		Not more than 30 ppm.
pH	Ph.Eur	3.0 – 7.0
Boron		Not more than 5 ppm.
Residue on ignition		Not more than 0,1% w/w
Sulphated ash		Not more than 0.2% w/w relative to the declared content of lactulose.
Assay	USP	62.7% - 69.3% (w/v) of lactulose
	Ph.Eur	62.7% - 69.3% (w/v) of lactulose
<u>Related substances</u>	USP	
Galactose		Not more than 16.0% w/w relative to lactulose
Lactose		Not more than 12.0% w/w relative to lactulose
Epilactose		Not more than 8.0% w/w relative to lactulose
Fructose		Not more than 1.0% w/w relative to lactulose
Tagatose		Not more than 4.0% w/w relative to lactulose

This data is for information purposes only and may change without notice.

La Palma Holland B.V. - J.H. Hisgenpad 349 - 1025 WK Amsterdam - the Netherlands

v.2026



CONTINUATION OF DATA SHEET

LACTULOSE CONCENTRATE 66.0% w/v USP/BP/Ph.Eur

<u>Related substances</u>	Ph.Eur
Galactose (impurity B)	Not more than 15.0% w/w relative to lactulose.
Lactose (impurity C)	Not more than 10.0% w/w relative to lactulose.
Epilactose (impurity A)	Not more than 10.0% w/w relative to lactulose.
Fructose (impurity D)	Not more than 1.0% w/w relative to lactulose.
Tagatose (impurity E)	Not more than 4.0% w/w relative to lactulose.
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Impurity F	Not more than 4.0% w/w relative to lactulose.
Impurity G	Not more than 1.5% w/w relative to lactulose.
Impurity H	Not more than 1.5% w/w relative to lactulose.
Unspecified impurity I	Not more than 0.5% w/w relative to lactulose.
Unspecified impurity J	Not more than 0.5% w/w relative to lactulose.
Unspecified impurity K	Not more than 0.5% w/w relative to lactulose.
Sum of impurities eluting after H	Not more than 1.3% w/w relative to lactulose.
Total impurities excl. impurities B and C	Not more than 12.0% w/w relative to lactulose.
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<u>Microbiology</u>	
Total aerobic count	Not more than 100 cfu per ml.
Yeasts and moulds	Not more than 10 cfu per ml.
Salmonella	Absent.
Escherichia coli	Absent.
Coliforms	Absent.
Pseudomonas aeruginosa	Absent.
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<u>Packing</u>	<ul style="list-style-type: none">- HDPE drums of 280 kilos net, 4 drums per plastic pallet.- IBC of 1300 and/or 1350 kg net.
<u>Storage</u>	Preferably store in its original packing, in a dry and cool warehouse, protected from light and humidity. Avoid subfreezing temperatures.
<u>Note</u>	Preparation and publication of this information has been done with all possible care. It is advised, however, that users convince themselves of the convenience to incorporate this product in their manufacturing process.

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