



LACTULOSE CONCENTRATE 66% w/v USP/BP

Code 31200a
v.1.06

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/PhEUR.

Specification:

TEST:	SPECIFICATION:
Characteristics	A colourless to brownish-yellow, clear or not more than slightly opalescent solution. Miscible in water.
Identification	A 10% v/v solution in laevorotatory A. in the test for related substances the retention time of the lactulose peak in the test corresponds to that of the standard B. a red precipitate of cuprous oxide is formed C. a red colour develops
Appearance of solution	the solution is clear and not more intensively coloured than the reference solution BY5
Refractive Index at 20° C	not less than 1.451
Sulphite	not more than 30 ppm
pH (Ph.Eur)	3.0 to 7.0
Boron	not more than 5 ppm
Lead	not more than 0.5 ppm w.r.t. declared lactulose content
Residue on ignition	not more than 0,1 % w/w
Sulphated ash	not more than 0,2 % relative to the declared content of lactulose
Methanol	not more than 30 ppm
Assay (Ph.Eur)	62,7 % w/v to 69,3 % w/v
Assay (USP)	62,7 % w/v to 69,3 % w/v

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

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**Related substances (Ph.Eur)**

Galactose	not more than 15 % w/w relative to lactulose
Lactose	not more than 10 % w/w relative to lactulose
Epilactose	not more than 10 % w/w relative to lactulose
Fructose	not more than 1 % w/w relative to lactulose
Tagatose	not more than 4 % w/w relative to lactulose

Related substances (USP)

Galactose	not more than 16 % w/w relative to lactulose
Lactose	not more than 12 % w/w relative to lactulose
Epilactose	not more than 8 % w/w relative to lactulose
Fructose	not more than 1 % w/w relative to lactulose

Microbiology	total aerobic count	less than 100 cfu per ml
	yeasts and moulds	less than 10 cfu per ml
	salmonella	absent
	escherichia coli	absent
	coliforms	absent
	pseudomonas aeruginosa	absent

Uses:

In the pharmaceutical industry: laxative and also in the treatment of hepatic encephalopathy. In babyfood and special health/geriatric foofs as prebiotic and/or stimulator of the growth of the intestinal flora.

Packing:

- Blue HDPE drums of 280 kilos net, 4 drums strapped on one wooden pallet.
- Alternative packaging: please advise your requirements.

Storage:

Preferably store in its original packing, in a dry and cool warehouse, protected from light and humidity. Store lactulose between 10 and 25° C.

Safety data:

No health hazards should exist, subject to normal standards of personal hygiene. No special instructions for first aid and no special precautions are necessary. Specific data available.

Note:

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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