

## Lactulose Solution

Revision date: 14.10.2011

### SPECIFICATION EP

The declared content of lactulose (according to CEP) is 670 g lactulose / l.

Tests	Limits or Requirements
<i>Characters</i>	Viscous liquid
<i>Identification</i>	Identification tests B, C, D
<i>Appearance of solution</i>	Clear and not more intensely coloured than reference solution BY <sub>5</sub>
<i>pH</i>	3.0 to 7.0
<i>Lactulose assay (HPLC)</i>	≥ 62.0 % w / v 47.5 to 52.5 % w / w
<i>Galactose corresponding to lactulose</i>	Not more than 15 %
<i>Lactose corresponding to lactulose</i>	Not more than 10 %
<i>Epilactose corresponding to lactulose</i>	Not more than 10 %
<i>Tagatose corresponding to lactulose</i>	Not more than 4 %
<i>Fructose corresponding to lactulose</i>	Not more than 1 %
<i>Sulfites</i>	Not more than 30 ppm
<i>Lead</i>	Not more than 0.5 ppm
<i>Sulfated ash</i>	Not more than 0.2 %
<i>Microbial contamination</i>	Total aerobic microbial count not more than 10 <sup>2</sup> CFU / g Total combined yeasts/moulds count not more than 10 <sup>1</sup> CFU / g Absence of <i>Escherichia coli</i>

Remark: Test for boron and methanol as basically required in the EP monograph omitted as neither substance is used in the production process. Would comply if tested.

## Lactulose Solution

Revision date: 14.10.2011

### SPECIFICATION USP

Tests	Limits or Requirements
<i>Characters</i>	Viscous, colourless to pale yellow-brownish liquid
<i>Identification</i>	Identification tests A, B
<i>Appearance of solution</i>	Clear and not more intensely coloured than < 0.300 A.U.
<i>pH</i>	2.5 to 6.5
<i>Refractive index <math>n_{20} / d</math></i>	$\geq 1.451$
<i>Density</i>	< 1.38 g / ml
<i>Specific optical rotation</i>	-17.0° to -25.0°
<i>Lactulose assay (HPLC)</i>	47.5 to 52.5 % w / w 95.0 to 105.0 % of the declared content
<i>Galactose corresponding to lactulose</i>	Not more than 16 %
<i>Lactose corresponding to lactulose</i>	Not more than 12 %
<i>Epilactose corresponding to lactulose</i>	Not more than 8 %
<i>Fructose corresponding to lactulose</i>	Not more than 1 %
<i>Total bacterial count</i>	Not more than 100 CFU / g
<i>Escherichia coli</i>	Negative
<i>Salmonella</i>	Negative

Remark: Test for boron and methanol as basically required in the EP monograph omitted as neither substance is used in the production process. Would comply if tested.

## Lactulose Solution

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### SPECIFICATION JP

Tests	Limits or Requirements
<i>Characters</i>	Viscous, colourless to pale yellow-brownish liquid
<i>Identification</i>	Identification tests A, B
<i>Appearance of solution</i>	Clear
<i>pH</i>	3.5 to 5.5
<i>Density</i>	1.320 to 1.360 g / ml
<i>Specific optical rotation</i>	-17.0° to -25.0°
<i>Lactulose assay (HPLC)</i>	50.0 to 56.0 % w / w
<i>Galactose corresponding to lactulose</i>	Not more than 11 %
<i>Lactose corresponding to lactulose</i>	Not more than 6.0 %
<i>Total bacterial count</i>	Not more than 100 CFU / g
<i>Escherichia coli</i>	Negative
<i>Salmonella</i>	Negative
<i>Total mould and yeast count</i>	Not more than 10 CFU / g