

## Lactulose Crystals SPECIFICATION EP

Revision date: 19.08.2011

Tests	Limits or Requirements
<i>Characters</i>	White or almost white crystalline powder
<i>Identification</i>	Identification tests B, C, D, E
<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>Specific optical rotation</i>	-46.0° to -50.0° on a.b.
<i>Water</i>	≤ 2.5 %
<i>Bulk density</i>	> 0.68 g / ml
<i>Particle size</i>	Max. 40 % < 100 microns
<i>Flowability</i>	< 30 sec.
<i>Lactulose assay (HPLC)</i>	97.0 to 102.0 % a.b.
<i>Related substances</i>	≤ 3.0 % a.b.
<i>Sulphites</i>	Not more than 30 ppm
<i>Lead</i>	Not more than 0.5 ppm
<i>Sulphated ash</i>	Not more than 0.2 %
<i>Microbial contamination</i>	Total viable aerobic count not more than 10 <sup>2</sup> CFU / g Absence of <i>Escherichia coli</i> per gram Absence of <i>Salmonella</i> per 10 grams

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.