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Certificate of Analysis

Product Name Lactulose, Ph. Eur. grade Glentham Code GC1952 **CAS Number** 4618-18-2 **EINECS** 225-027-7 MDL Number MFCD00151469 PubChem SID 310275685 **Batch Number** 819EXJ Molecular Weight 342.30 Molecular Formula $C_{12}H_{22}O_{11}$ +20°C Storage Temp.

Property	Specification	Batch 819EXJ
Physical Description	White to almost white crystalline powder	White crystalline powder
Identification	According to Ph. Eur.	Conforms
Solubility	Freely soluble in water, sparingly soluble in methanol, practically insoluble in toluene	Conforms
Solubility (6% in water)	Clear, colourless solution	Clear, colourless solution
рН	3.0 - 7.0 None	5.7
Specific Optical Rotation	-50.046.0 °	-49.8°
Impurity C	≤ 2.0% (lactose)	≤0.5%
Any Other Individual Impurity	≤ 0.5%	Conforms
Total Impurities	≤ 3.0%	Conforms
Methanol	≤ 50ppm	Conforms
Boron (B)	≤ 9ppm	Conforms
Water	≤ 2.5%	0.7%
Sulphated Ash	≤ 0.1%	Conforms
Total Aerobic Microbial Count	≤ 100CFU/g	Conforms
E. Coli	Absent	Absent
Assay (HPLC)	98.0 - 102.0 % (anhydrous basis)	100.5%
Pharmacopoeia Specification(s)	Ph. Eur.	Conforms

Specification Version v1.1

Manufacture Date 2022-11-01

Re-Test Date 2031-01-20

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

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