



Lactose Purity According to Pharmacopoeia

The US and the European pharmacopoeias demand the analysis of the purity of lactose monohydrate polarimetrically. Determining the specific rotation with an MCP polarimeter from Anton Paar ensures high-quality products.

Lactose monohydrate in compliance with EU/US pharmacopoeias

Lactose, also referred to as milk sugar, is widely used in the pharmaceutical industry. As lactose has excellent compressibility properties it is helpful to use when forming tablets. Further applications are for dry-powder inhalations, to treat obstipation, as a pharmaceutical adjuvant and as an additive and binder in the food industry.

The US and European pharmacopoeias demand the determination of the specific rotation of lactose monohydrate. The procedure is as follows: 10 g lactose monohydrate is dissolved in 80 mL of water by heating to 50 °C. After the solution has cooled down, 0.2 mL 6 M NH₄OH are added. 30 min later, the solution is diluted to 100 ml with water. The specific rotation has to be between +54.4 mL·°/(dm·g) and +55.9 mL·°/(dm·g) at 20 °C, 589.3 nm and a sample cell length of 1 dm.

MCP polarimeter family from Anton Paar - 40 years of experience

The MCP polarimeters from Anton Paar are ideal for determining the specific rotation of lactose monohydrate. MCP 100, 200, 300 and 500 are all in compliance with international pharmacopoeias, offering an optimal solution for every user.

- **21 CFR part 11:** The MCP polarimeters are in compliance with 21 CFR part 11 including user-level management and data storage.
- **Peltier temperature control:** The specific rotation is temperature-dependent. Peltier temperature control with an accuracy of up to ±0.03 °C makes a water bath unnecessary.
- **Filling Check™:** A built-in camera is available which verifies the correct filling of the sample cell in order to avoid air bubbles or smears.
- **Toolmaster™:** The sample cell and quartz control plate are automatically identified by the MCP.



Good to know

The MCP polarimeters from Anton Paar are ideal to determine the specific rotation of lactose monohydrate.

Other Anton Paar instruments relevant for the application

The Abbemat refractometers from Anton Paar now have the new customer function "Lactose (Wolf, 1966)" which directly converts the refractive index of lactose-water solutions into concentration [g/100 g].



Do you have any questions?

Contact Anton Paar directly:

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