

Determination of Lactose (Surrogate) In Air and Wipe Samples

Summary

The following describes the sampling procedures for the determination of airborne lactose. Lactose is commonly used as a surrogate in place of the active pharmaceutical ingredient (API) for verifying the effectiveness of containment systems handling these materials without having the health concerns of handling the actual API. Using an AIHA accredited contract laboratory keeps the objectivity and independence of the testing intact, benefiting both the vendor and user of the containment equipment.

Lactose General Information

CAS: 63-42-3

Molecular Weight: 342.30

Molecular Formula: $C_{12}H_{22}O_{11}$

Sample Collection

Media	Flow Rate	Sampling	Reporting Limit (LOQ)
25 mm PTFE	2 - 4 LPM	15 Min to 8 Hours	2 ng
37mm GFF moistened with DI water	N/A	Wipe $\leq 25 \text{ cm}^2$	10 ng
Texwipe Swab moistened with DI water	N/A	Wipe $\leq 25 \text{ cm}^2$	10 ng

- At least one cassette that has no air drawn through it should be included as a field blank for air samples.
- At least one filter (wetted) that has not been used to sample a surface should be included as a field blank for wipe samples.
- Collected samples should be returned to the laboratory as soon as possible.

LOQ as a Function of Sample Time

Sample Time (Min/L)	LOQ (ng/m^3)
15 min @ 2 L/m (30 L)	67
15 min @ 4 L/m (60 L)	33
30 min @ 4 L/m (120 L)	17
1 h @ 2 L/m (120 L)	17
4 h @ 2 L/m (480 L)	4.2
8 h @ 2 L/m (960 L)	2.1

Analytics is eager for the opportunity to work with you on your lactose testing needs. Our organization, personnel, dedicated project management/customer service, coupled with our data quality, instrumentation and facilities can fully support your testing requirements.

For additional information, please contact Bill DeMartin at wjdemartin@comcast.net, or 856-627-4767.