



Trinity Consultants is a leading global environmental consulting firm that brings 50 years of experience providing services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Trinity has the technical expertise and acute industry knowledge to provide optimal solutions to highly complex pharmaceutical development, process, safety, and facility design challenges.

Surrogates are material substitutes for hazardous or potent materials in the evaluation of process containment, controls, and operating procedure in life sciences environments.

### Analytical Methods Employed – The SafeBridge® Advantage

The occupational exposure limits and acceptable surface limits (OELs and ASLs) specified by the manufacturer are commonly in the range of ng/m<sup>3</sup> or below 1 µg/cm<sup>2</sup> and, therefore, require highly sensitive analytical methodologies. SafeBridge®'s laboratory, accredited by the American Industrial Hygiene Association, employs LC/MS/MS, ELISA, and HPLC analytical technologies.

Our methods achieve high specificity, ultra-sensitivity and a high recovery rate through the proper choice of filter media and extracting procedures as well as the optimization of air sampling parameters. The methods are validated with respect to analytical detection limits, precision, and accuracy. Data on the stability of compounds relative to airflow volume and storage conditions are contained in these methods. The SafeBridge® advantage is that we employ the most sensitive techniques in the industry to detect potent drugs at very low concentrations in the workplace – to quantitation limits as low as 5 picograms/filter. SafeBridge®'s analytical laboratory operates just as if it is our clients' very own internal industrial hygiene laboratory.

#### Here are the most commonly used process surrogates, with SafeBridge®'s industry-leading Limit of Quantitation (LOQ):

- **Naproxen Sodium LOQ:** 5 picograms/sample (0.005 nanograms/sample)
- **New Updated Limit Lactose LOQ:** 50 picograms/sample (0.05 nanograms/sample)
- **Acetaminophen/Paracetamol LOQ:** 50 picograms/samples (0.05 nanograms/sample)

- **Insulin LOQ:** 200 picograms/sample (0.2 nanograms/sample)
- **Mannitol LOQ:** 500 picograms/sample (0.5 nanograms/sample)

#### Criteria used to select an appropriate surrogate-

- Availability and sensitivity of the sampling/analytical method
- Low risk to personnel (lack of inhalation toxicity)
- Cost and availability of surrogate material
- Quality concerns (Good Manufacturing Practices)
- Cleanability
- Challenge (the dustiness of the surrogate should be appropriate for the application)

### Our Capabilities

SafeBridge®, a Trinity Consultants team, performs surrogate monitoring with our field industrial hygiene staff and analyzes samples for verification of containment systems.



#### CONTACT OUR TEAM!

For more information about how we can help your organization, please contact us.

**Trinity Consultants | SafeBridge**  
P 650.961.4820 / [info@safefridge.com](mailto:info@safefridge.com)

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