



Custom Endotoxin Service - Low Endotoxin Recovery (LER)

Demasking protocol development and validation for biopharmaceutical formulations containing surfactants

Hyglos has unique expertise in the processes behind endotoxin masking and is specialized in developing and validating custom demasking protocols. The new methods **Endo-RS®** and **EndoLISA®** combined provide the technological basis for accurate determination of endotoxins in biopharmaceuticals containing surfactants (e.g. polysorbate). As biopharmaceutical formulations differ in concentrations and compositions, for each formulation an optimized protocol is needed.

With extensive experience and strong customer orientation, Hyglos Custom Endotoxin Service is well positioned to supply the Pharma and Biotech industry with services customized to your quality control and regulatory needs¹.

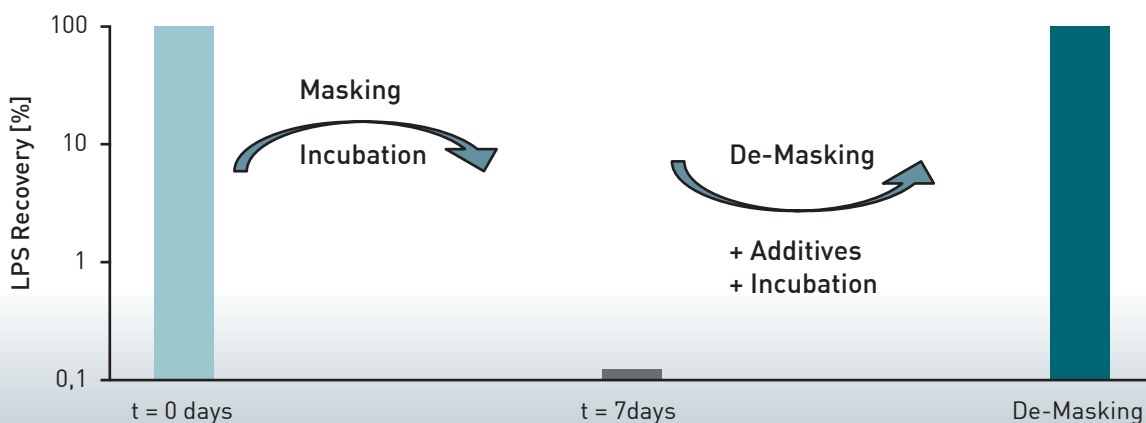


Figure: Formulation-specific de-masking protocol (Reich et al., Hyglos GmbH, 2014)

Custom Endotoxin Service LER includes:

- Formulation-specific evaluation (Masking Monitoring)
- Development of a dedicated demasking protocol using Endo-RS® and EndoLISA®
- Validation of final test protocol (GMP-compliant)

¹ In order to verify the reliability of the endotoxin assay, time-dependent endotoxin spiking studies with undiluted drug product lots are required by the FDA. The drug product lots are spiked with specified endotoxin levels, and held for several days (depending on matrix) before being assayed.

Contact Form Custom Endotoxin Service LER

Complete this form and send to Hyglos GmbH:

Fax: +49 (0) 8158 9060 210

E-mail: info@hyglos.de

What is your primary industry?

Pharmaceuticals (small molecules)

Biopharmaceuticals

Medical Devices

Other (please specify):

What kind of service do you require?

Masking Monitoring

Demasking Protocol Development

Validation

I would like to be contacted by Hyglos for:

Receiving further information

Meeting (WebEx/face-to-face)

Method demonstration

Quotation and terms

Name: _____

Job title: _____

Company: _____

Address: _____

City/State/Zip: _____

E-mail: _____

Phone: _____ Fax: _____

Find out more on www.hyglos.com

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03.04.02

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