Endotoxin Recovery Kit (Surfactant)

A Toolbox for Demasking Endotoxin in Pharmaceutical Formulations exhibiting Low Endotoxin Recovery (LER)

Endo-RS® is a unique sample preparation method addressing masking of endotoxin at the root cause and enabling complete endotoxin recovery in biopharmaceutical drug formulations typically containing protein in high concentrations and non-ionic surfactants such as polysorbate in combination with chelating agents.

In scientific studies it has been demonstrated that such formulations are likely to change the aggregate state of the analyte endotoxin in such a way that it is no longer accessible for detection with Factor C-based endotoxin tests such as Limulus Amebocyte Lysate (LAL) and Recombinant Factor C (rFC).

Endo-RS® provides the essential reagents and a detailed guideline for evaluating and establishing an optimized endotoxin demasking protocol for each individual formulation. This includes a screening process in order to determine the appropriate amounts and concentrations of demasking reagents.

Endo-RS® has been developed in combination with the **EndoLISA®** Endotoxin Detection Assay to ensure compliant and accurate results in hold time studies[1*] as well as routine quality control testing.

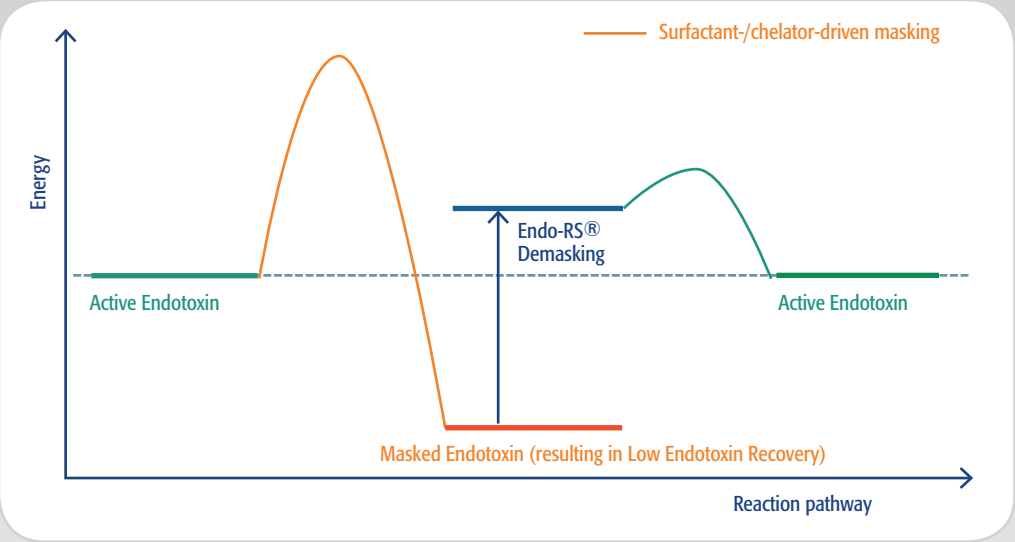
Endo-RS® at a Glance

- Full quantitative recovery of endotoxin in biopharmaceutical samples affected by LER
- Demasking independent of storage time and endotoxin concentration
- Detailed technical guidelines provided
- All needed reagents are included in the kit for developing a formulation-specific sample preparation protocol in combination with the **EndoLISA®** assay. It is possible to apply **Endo-RS®** in combination with conventional LAL, but not directly without interface optimization. Contact us to find out how we can help you to develop a protocol according to your needs.

[1*] In order to verify the reliability of the endotoxin assay, time-dependent endotoxin hold time 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. Hyglos provides compliant hold time studies as service.

Endo-RS® Work Principle

Rearrangement of the masked endotoxin state into a Factor C-active state requires addition of energy to the system (based on Reich *et al.* 2014):



Endo-RS® Procedure for Establishing a Routine Protocol

1. Screening
Selection of the agents suitable for the specific formulation

2. Optimization
Titration of agents to optimal levels - adjustment of protocol

3. Validation
Validation of method according to standard BET criteria (EP,USP,JP)

Endo-RS® Kit Components

Cat. No. 609065

Reagent amounts sufficient for demasking minimum 25 samples included in the kit:

	Component	Function
A.	Buffer	Buffer for pH adjustment of samples
B.	Disturber	Agent for destabilization of LPS-Masker-Complex
C.	Adsorber	Agent for surfactant adsorption
D1.	Modulator	Agent for supporting Reagent E Reconfigurator
D2.	Modulator	Agent for supporting Reagent E Reconfigurator
E.	Reconfigurator	Agent for LPS aggregate structure formation
F.	Endotoxin	Endotoxin Standard CSE (LPS from *E. coli* O55:B5)
G.	Water	Water free of detectable levels of endotoxin for reconstitution

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