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 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.

"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:

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