

ENDOTOXINS (lipopolysaccharides)

ACILA Dr. Weidner GmbH offers endotoxins (lipopolysaccharides or LPSs) for various applications, including the Limulus-Amebocyte-Lysate testing (LAL test) and the Pyrogen tests. They can also be used as bioindicators as required for the validation of depyrogenation processes or ultrafiltration.

Endotoxins from different species of bacteria obviously contain different amounts of lipid A. Our endotoxins are prepared according to the WESTPHAL method and highly purified. Opposite to most endotoxin preparations, those of ACILA do not contain any fillers.

1. REFERENCE STANDARD ENDOTOXIN (RSE)

The different Pharmacopoeias (Europe, USA, Japan), the World Health Organisation (WHO) and the Food and Drug Administration (FDA) differentiate a Reference Standard Endotoxin (RSE) from a Control Standard Endotoxin (CSE).

For reference, endotoxin units were defined to have identical activities, when the Limulus Amebocyte Lysate test (LAL test) was harmonized as far as the three main Pharmacopoeias were concerned in 1997: United States Pharmacopoeia (USP), European Pharmacopoeia (EP), and Japanese Pharmacopoeia (JP).

1 I.U. (International Unit and EP Unit) = 1 E.U. (Endotoxin Unit, FDA) = 1 USP Unit

These RSE's, however, are still found with different product names and with their individual units depending on their origin.

LPS	Product name	Institution of origin	Units
<i>E. coli</i> O113	2 nd Int. Standard	WHO	10,000 I.U./vial
<i>E. coli</i> O113	BRP current lot	European Pharmacopoeia	10,000 I.U./vial
<i>E. coli</i> O113	USP current lot	USP	10,000 I.U./vial
<i>E. coli</i> O113	EC current lot	FDA	10,000 I.U./vial

The International Standard of the WHO and the EC current lot of the FDA are available only for certain reference laboratories or producers of Limulus lysate.

The other RSE's (the European BRP and the USP current lot) may be purchased either at the office of the respective Pharmacopoeias or from ACILA Dr. Weidner GmbH.

REFERENCE STANDARD ENDOTOXINS (lyophilized with fillers)

Article No°	Product name	Institution of origin	Price in €
1220200	Lot G4	USP	on request
1220211	BRP 5	European Pharmacopoeia	on request

2. CONTROL STANDARD ENDOTOXIN (CSE)

Control Standard Endotoxins (CSE) are working standards with individual activities depending on the lot of lysate and the method of LAL testing used. Therefore, the activity of a given CSE must be compared to a RSE prior to routine testing. Most producers of LAL provide certificates for their individual lysate lots as far as determined with a given CSE.

CONTROL STANDARD ENDOTOXINS

Article No°	Product name	LPS	Amount	Price in €
1220302	NP4 (liquid)	<i>S. abortus equi</i>	Vial with 1.1 ml and 100 ng/ml	on request
1220305	LPS <i>E.coli</i> O55:B5	<i>E.coli</i> O55:B5	Vial with 10 ng	on request

3. ENDOTOXINS as BIOINDICATORS for PROOF of DEPYROGENATION or for the VALIDATION of ULTRAFILTRATION

The endotoxins listed below were produced without additives to increase their heat resistance. If products have been lyophilised, vials may seem to be empty due to their low contents of LPS. On the other side, many endotoxin preparations contain fillers (e.g. lactose) to increase solubility. These lyophilisates look well filled as the official RSEs.

Lipids of *Salmonella abortus equi* are sterile aqueous solutions.

We may draw your attention to the particular filling activities of our production team.

According to the needs of our clients, ACILA AG fills endotoxins of any concentration into sterile and endotoxin-free vials, ampoules, bottles of various sizes or even syringes to prepare bioindicators for depyrogenation studies. Contact us for more information.

BIOINDICATORS and other ENDOTOXINS

Article No°	Product name	I.U./Vial Depending on test and lysate	Vials/Box	Price in €
1230320	LPS <i>E. coli</i> O55:B5, lyophilised 2 mg	> 6,000,000	1	on request
1230315	LPS <i>E. coli</i> O55:B5, lyophilised 1 mg	> 3,000,000	1	on request
1230365	LPS <i>E. coli</i> O55:B5, lyophilised 10 µg	100,000	10	on request
1230360	LPS <i>E. coli</i> O55:B5, lyophilised 5 µg	50,000	10	on request
1230355	LPS <i>E. coli</i> O55:B5, lyophilised 1 µg	10,000	10	on request
1230350	LPS <i>E. coli</i> O55:B5, lyophilised 0.5 µg	5,000	10	on request
1230335	LPS <i>E. coli</i> O55:B5, lyophilised 0.1 µg	1,000	10	on request
1230010	LPS <i>S. abortus equi</i> , liquid 5mg / 5 ml	5 mg / 5 ml	1	on request

