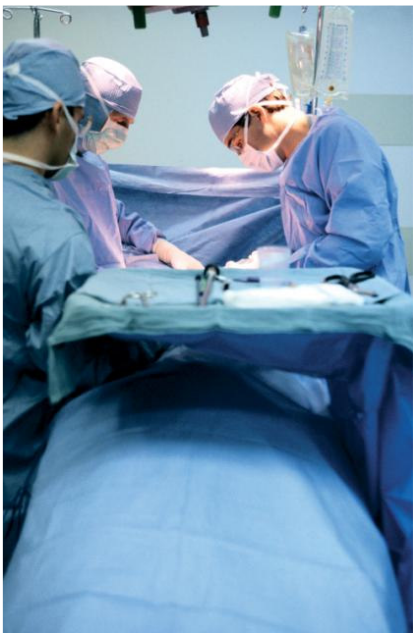
SCOOP
THE LATEST TRENDS, SERVICES & PROMOTIONS

HEALTHCARE AND COSMETICS, SGS HONG KONG APR, 2013

BACTERIAL ENDOTOXIN TEST (BET) FOR STERILE AND PHARMACEUTICAL PRODUCTS



SOURCE OF ENDOTOXINS

Pyrogen is a substance that can give rise to an increase in body temperature, shock and even death when it is in contact with blood and cerebrospinal fluid. Bacterial endotoxin is a pyrogen which originates from Gram-negative bacteria such as *E. coli*. This endotoxin is found within the exterior membranes which consist of lipopolysaccharides, and it is normally not secretory but only released during cell division and lysis of cells.

Endotoxin released from Gram-negative bacteria is the main reason of contamination of pharmaceutical products, and as a result of this, endotoxin test is normally performed on sterile product, medical device and pharmaceutical product which is to be injected or implanted into body, so as to prevent bringing adverse effect to human.

COMMON TEST METHOD OF BACTERIAL ENDOTOXIN

Limulus Amebocyte Lysate (LAL) is a common test method for Endotoxin. One of the quantitative techniques of LAL Endotoxin test is Kinetic Chromogenic technique. Chemophore, which gives colors, will be released from chromogenic peptide during the reaction. This technique is to determine the cloudiness by the loss of light intensity and by measuring the time required for the absorbance of reaction mixture reaching a predetermined level, or the rate of color development.

EUROPEAN PHARMACOPOEIA <2.6.14> and UNITED STATES PHARMACOPEIA <85> are the established test methods for endotoxin in EU and US market respectively. Endotoxin limit is different for different products. Here are some examples of endotoxin limit requirement for different pharmaceutical products.

Examples of Endotoxin Level Requirement	
Insulin	10 EU/mg
Sodium Chloride Solution for Injection	1.0 EU/mL
Sterile Water for Inhalation	0.5 EU/mL
Water for Irrigation	0.25 EU/mL
Urea for injection	0.003 EU/mg

Should you have any queries, please contact our customer service representatives for details.

FOR ENQUIRIES:

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