

Control of WFI and Clean Steam Systems for Bacterial Endotoxins



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Bacterial endotoxin presents a risk to several classes of pharmaceutical product, with parenteral products at the greatest risk. Bacterial endotoxin is the lipopolysaccharide (LPS) component of the cell wall of Gram-negative bacteria. It is pyrogenic and it is a risk to patients who are administered intravenous and intramuscular preparations. The pathological effects of endotoxin, when injected, are a rapid increase in core body temperature followed by extremely rapid and severe shock. In some cases, death can occur (1).

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