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Qualification of Tunnel Sterilizing Machine

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Abstract: Depyrogenation devices, such as tunnels, are used in the pharmaceutical industry to prepare components for aseptic filling. To qualify such devices, various pharmacopoeias require depyrogenation devices to be periodically challenged with high levels of bacterial endotoxin. Although the pharmacopoeias state the acceptance criteria, little consideration is given to the practical approach. This work discusses the theoretical concept of depyrogenation and the various tests performed for the qualification of Depyrogenation Tunnels.

Key words: Depyrogenation, Bacterial Endotoxin, Performance Qualification.

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