[W-3] [10/22/2004(Frl) 11:10-11:50/Room 205]

Parametric Release of Terminally Heat Sterilized Products

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Terminally heat sterilized products are typically release for distribution on the basis of a satisfactory review of the sterilization cycle records and sterility test results.

This has been generally accepted practice in the pharmaceutical industry for decades.

But because the sterility test is a flawed test method with substantial limitation, the assured method to determine success on sterilization process is through cycle monitoring and record review to ensure that the sterilization cycle parameters were within their validated specifications.

In 1985, FDA approved supplemental new drug applications for large volume parenteral drug products of Baxter company, which substituted parametric release for routine lot by lot end-product sterility testing. Parametric Release (PR) is defined as a sterility release procedure based upon effective control, monitoring, and documentation of a validated sterilization process cycle in lieu of release based upon end-product sterility testing.

All parameters within the procedure must be met before the lot is released.

All parameters are

1. The sterilization process cycle
2. Integrity for each container/closure system
3. Bioburden testing
4. Chemical or biological indicator.

The regulation for PR was registered in various countries including EU and Japan and approved some products with this regulation.

In Korea, it is also necessary to be adopted in the relevant regulation and approved actually in order to assure sterility of terminally heat sterilized products.