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~~Pharmaceutical Microbiology Manual - Food and Drug ...~~

For purposes of this document, the term OOS results includes all test results that fall outside the specifications or acceptance criteria established in drug applications, drug master files (DMFs ...

~~Investigating Out-of-Specification Test Results for ...~~

1 . Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production . This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic.

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Guidance for Industry Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production.-Phase I and Phase II of an Out of Specification

Investigation.-Examine the new FDA “ attitude ” that is being taken with non-sterile product.-Identify the OOT and OOS regulatory concerns in a cGMP environment.

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Microbiology laboratories should be separated from production areas and have an air handling system separated from the production areas. Microbiology laboratories should be designed and have sufficient space to suit the operations carried out in them and to avoid mix ups, contamination and cross contamination. If necessary,

Guidance for Industry: Microbiology Laboratories (Version 4.0)

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-Examine the new FDA “ attitude ” that is being taken with non-sterile product. -Identify the OOT and OOS regulatory concerns in a cGMP environment. -Review the microbiological issues that may occur within Incoming Raw Materials, In-Process and API phases.

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