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products, Dr. Dunnigan of the Bureau of Medicine of the FDA commented on the health hazard.

Microbiological Pharmaceutical Quality Control Labs (7/93 ...

In a recent court decision the judge used the term "out-of-specification" (OOS) laboratory result rather than the term "product failure" which is more

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common to FDA
investigators and
analysts.

Pharmaceutical Quality Control Labs (7/93) | FDA

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),...

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investigation of out-of-
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results is an important
part of the work

undertaken by the

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Out Of Specification (OOS) :- The all test results which goes outside the specification or acceptance criteria established in Drug Dossiers, Drug Master files, Its official Pharmacopeias, Or the manufacturer comes Under Out of Specification (OOS).

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FICTION

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The OOS process is not applicable for In-process testing while trying to achieve a manufacturing process end-point i.e. adjustment of the manufacturing process. (e.g. pH, viscosity), and for studies conducted at variable parameters to check the impact of

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drift (e.g. process validation at variable parameters). Out-of-Specification (OOS) Result -

Out of Specification & Out of Trend Investigations (MHRA ...

OOS (Out of Specification) result from the microbiology lab. The very ... it seems that the FDA (US Food and Drug Administration) is

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curious when it becomes apparent that the ... [11] or the PIC/S Guide to Inspections of QC Lab [7]. If the documentation can meet these requirements,

Successful Microbiological Investigations

Managing Out of Specification Result Investigations in Quality Control. Regulations are very

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sensitive as to how any out-of-specification laboratory test result is treated. Laboratories are required to have written procedures on the steps to take when any result does not meet specifications (generally known as OOS rules).

Managing Out of Specification Investigations in Quality ...

Ankur Choudhary is

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OOS Investigation

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Flowchart : Pharmaceutical Guidelines

The US FDA guidance states that OOS investigation must be conducted wherever an OOS result is generated. The purpose of such an investigation is to determine a root cause for the OOS result. The root cause must be due to the measurement process or the manufacturing process.

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