



OUT OF SPECIFICATION

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ISO 17025:2005

- 4.9 Control of nonconforming testing and/or calibration work
- 4.9.1 The laboratory shall have **a policy and procedures** that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer.

WHO : Good practices for national Pharmaceutical control Laboratories

- 18 Evaluation of test results
- 18.4 An SOP should be in place for the conduct of an investigation of an OOS test result. The SOP should give clear guidance on the number of retests allowed (based on sound statistical principles). All investigations and their conclusions should be recorded.

OOS results

- all test results that fall outside the specifications or acceptance criteria established in drug dossiers, drug master files (DMFs), official pharmacopoeias, or by the manufacturer.

(WHO : Good practices for national Pharmaceutical control Laboratories)

OOS results

- all test results that fall outside the specifications or acceptance criteria established in drug applications, drug master files (DMFs), official compendia, or by the manufacturer.

(US FDA : Guideline for Industry Investigating OOS Testing Results for Pharmaceutical Production)

US FDA : Guideline for Industry Investigating OOS Testing Results for Pharmaceutical Production

- The purpose of the investigation is to determine the cause of the OOS result.
- The source of the OOS result should be identified either as an aberration of the measurement process (laboratory error) or an aberration of the manufacturing process.

US FDA : Guideline for Industry Investigating OOS Testing Results for Pharmaceutical Production

- **PHASE I: LABORATORY INVESTIGATION**
 - should include an initial assessment of the accuracy of the laboratory's data.
- **PHASE II: FULL-SCALE OOS INVESTIGATION**
 - consist of a production process review and/or additional laboratory work

SOP OOS (no. 2200026)

- **Definition**

- **Out of Specification (OOS)** means the test result that falls outside the specifications or acceptance criteria which has been specified in the official compendia monographs or the finished product specification in registration dossiers.

SOP OOS (no. 2200026)

- **Purpose**

- This SOP describes the procedure for investigating out of specification test result.

- **Application**

- This procedure is applicable to the test result that falls outside the specifications or acceptance criteria

SOP OOS (no. 2200026)

- **Definition**

- **Laboratory error** is the cause of OOS result which may occur from instrument, reagent, reference standard, environment condition, test method, analyst and calculation within laboratory.

Data record and Used document

- Out of Specification Check List
(WS 2200026/1)
- Out of Specification Report
(WS 2200026/2)
- List of Out of Specification
(WS 2200026/3)

PROCEDURE SOP. OOS (no. 2200026)

1. When the OOS result is found, analyst should inform laboratory supervisor immediately.
2. Before start the OOS investigation, analyst should inform the quality manager by using the Out of Specification Report (WS 2200026/2) to record and number the OOS.

PROCEDURE SOP. OOS (no. 2200026)

3. Investigation should be conducted by the analyst and laboratory supervisor by using the Out of Specification Check List (WS 2200026/1).
4. Laboratory supervisor assigns an analyst to perform the test.
5. Details of the retest procedure should be written by the analyst or assigned person and then approved by laboratory supervisor.

PROCEDURE SOP. OOS (no. 2200026)

6. The analyst or assigned person should perform the test by using the approved procedure.
7. The analyst or assigned person prepares the test report for approval by laboratory supervisor.
8. In case that the cause of OOS could be identified (If conclusion can be done), the report should be approved by laboratory supervisor.

PROCEDURE SOP. OOS (no. 2200026)

9. If there is inadequate data to evaluate the investigating result (suspect result), the investigation should repeat following the process 4-8.
10. When the retest has already been performed and the cause of OOS result cannot be identified (If conclusion cannot be done), laboratory supervisor should inform technical management team.

PROCEDURE SOP. OOS (no. 2200026)

11. Technical management team considers and evaluates the investigating result and all the data for conclusion and report.
12. When the OOS report is complete, it should be kept in the sample report and the copy should be sent to the quality manager. The OOS will be recorded in the List of Out of Specification (WS 2200026/3) by the quality manager.

SOP OOS (no. 2200026)

- **DEFINITION**

- **Technical Management Team** consists of director, expert pharmacists, quality manager and heads of laboratories/centers.

Retest and reporting procedure

- I. When the cause of OOS result can be identified as a **laboratory error**.
 - Retest should be performed on **the original sample by the same analyst**.
 - Reporting procedure: the original test result will be invalid. The **retest result should be reported**.
 - All of the **original data should be retained**, and an explanation should be written.

Retest and reporting procedure

2. In case of the cause of the OOS result could not be identified as a laboratory error:
 - Retest should be performed by **a different analyst.**
 - The retest should not be done more than 3 times including the test by the first analyst.

Retest and reporting procedure

- Reporting procedure can be defined into 2 cases:
 - ❖ If the retesting result has **confirmed the OOS** result, the **original OOS result should be reported**. If the RPD of the mean of the original result and the mean of the retest result is less than 3%, it can conclude that the retest result has confirmed the original result. .The RPD may be justified scientifically.
 - ❖ If the OOS result could **not be confirmed** or the **investigation could not be concluded**, the OOS result should be further considered by the technical management team.



THANK YOU