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N.B. This OMCL Quality Management System document is applicable to members of the European OMCL Network only. Other laboratories might use the document on a voluntary basis. However, please note that the EDQM cannot treat any questions related to the application of the documents submitted by laboratories other than the OMCLs of the Network.

EVALUATION AND REPORTING OF RESULTS

Note: Mandatory requirements in this guideline are defined using the terms "shall" or "must". The use of "should" indicates a recommendation. For these parts of the text, other appropriately justified approaches are acceptable. The term "can" indicates a possibility or an example with non-binding character.

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1. Introduction

This document defines the basic principles for evaluation and reporting of results and is intended to give guidance for the interpretation of the requirements of ISO/IEC 17025:2017 clauses 7.7 Ensuring the validity of results and 7.8 Reporting of results. According to ISO/IEC 17025:2017 clause 7.7, the laboratory shall have a procedure for monitoring the validity of results, the resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. According to ISO/IEC 17025:2017 clause 7.8, the results shall be provided accurately, clearly, unambiguously and objectively [1].

This document also defines the framework and basic principles for decision rules which, according to ISO/IEC 17025:2017, shall be applied in the statement of conformity (unless the rule is inherent in the specification or standard) by OMCLs [1].

The OMCL shall operate within a quality system based on ISO/IEC 17025:2017 to ensure the validity of the results generated. Testing results and statements of conformity obtained by OMCLs

are communicated to the Competent Authorities and within the OMCL Network. The results of the OMCL testing may have significant consequences for the products involved, especially if a sample is found to be out of specification (OOS). Measures taken by the Competent Authority may include recalls, batch rejection, thorough production investigations and refusal of marketing authorisation (in pre-licensing evaluations). On the other hand, unidentified product deficiencies may have a significant impact on patient or public health.

The core document is complemented with annexes listed hereunder:

Annex 1. Rounding/significant figures

Annex 2. Evaluation of results from quantitative testing

Annex 3. Verification of Initial out-of-specification (OOS) results

- *Annex 3.1. General Introduction*
- *Annex 3.2. Verification of Initial out-of-specification (OOS) results in quantitative testing*
- *Annex 3.3. Verification of Initial out-of-specification (OOS) results in qualitative testing*
- *Annex 3.4. Special considerations from animal testing in connection with verification of OOS results*

In particular, Annexes 2 and 3 contain examples for specific decision rules that were agreed within the OMCL Network.

Other approaches than those described in the Annexes are possible, if they are supported by an appropriate and documented scientific justification. The content of this guideline is linked to the OMCL Guidelines “Validation/verification of analytical procedures”, “Evaluation of measurement uncertainty” and “Validation of computerised systems” [2-4].

2. Scope

This guideline is applicable to all activities within the OMCL Network, including compliance testing and other testing activities (e.g. screening, analysis of unknown products, trace analysis) related to qualitative, quantitative and semi-quantitative testing of chemical and biological pharmaceutical substances, medicinal products for human and veterinary use and herbal products. Compliance testing includes: market surveillance studies (MSS), testing of centrally authorised products (CAP), testing of products authorised with the mutual recognition procedure and decentralised procedure (MRP/DCP) or national authorisation, Official Control Authority Batch Release (OCABR), pre-licensing evaluation and pharmaceutical preparations prepared in pharmacies. This guideline may also be applicable for the testing of suspect and falsified products.

3. Glossary and definitions (also used in the text of the Annexes)

Compliance testing: tests performed using official or validated analytical procedures to verify that a pharmaceutical substance or medicinal product examined conforms to the specification limits given in the monograph or in the marketing authorisation.

Correction: action to eliminate a detected nonconformity [5].

Corrective action: action to eliminate the cause of a nonconformity and to prevent recurrence [5].

Decimal places: the position of a digit to the right of a decimal point.

Decision rule: rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement [1].

Independent determination: performance of the whole experiment, considering the factors which are critical to the method variability (for example sample preparation) and generation of a result for one test sample. One independent determination can be obtained from one replicate/observation or by averaging a number of replicates.

Measurement uncertainty (MU): a parameter associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the measurand [6].

Outlier: value that considerably differs from other values or the mean value, detected by a statistical method [7].

Out-of-specification result: result not in compliance with the specification limits given in an official standard (numerical or descriptive limits) or manufacturer's dossier.

Reanalysis: reanalysis of a previously tested sample or sample preparation that has been stored under defined conditions to ensure sample integrity and stability.

Replicate: one of a number of observations obtained from one test sample preparation.

Reportable result: analytical testing result fulfilling validity criteria predefined in the written approved test method and derived from one full execution of that method, starting from the original sample. A reportable result may be obtained from a single independent determination or may be calculated as an average from several independent determinations in order to reduce the error, as defined in the test method. A reportable result is a valid testing result, which is compared with the criteria defined in the specification, but will not necessarily be reported in the final test report [7].

Re-sampling: taking an additional representative sample of a batch. This can be necessary if, for example, there is insufficient material in the original sample, or an integrity problem with the original sample. Resampling should be done in accordance with the approved sampling procedures and plan in force and implemented for the initial sampling, unless the investigation has demonstrated these were not adequate. In this case, a new sampling plan is defined, documented and approved"

Retest: analysis of additional units from a batch of previously tested product. Additional units may have been collected as part of the sampling process for the original sample, or may be from a new sample collected from the same batch.

Sample: a representative portion of a substance or material or product for analysis.

Significant figures: digits of a number that are used to express it to the required degree of accuracy, starting from the first non-zero.

Specification limit: specified upper or lower bound of permissible values of a property [8].

Specification limits (Tolerance limits, TL): appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a drug substance or drug product should conform to be considered acceptable for its intended use [9].

Specification: a list of tests, references to analytical procedures and appropriate acceptance criteria which are numerical limits, ranges or other criteria for the tests described. It establishes the set of criteria to which a drug substance or drug product should conform to be considered acceptable for its intended use. "Conformance to specifications" means that the drug substance and/or drug product, when tested according to the listed analytical procedures, will meet the listed acceptance criteria. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities [9] or laid down in the Ph. Eur. or other compendia.

4. Evaluation of testing results

4.1 Testing results

The testing results in OMCLs are obtained from qualitative, quantitative and semi-quantitative analyses performed as part of compliance or other testing activities (e.g. screening, analysis of unknown products, trace analysis).

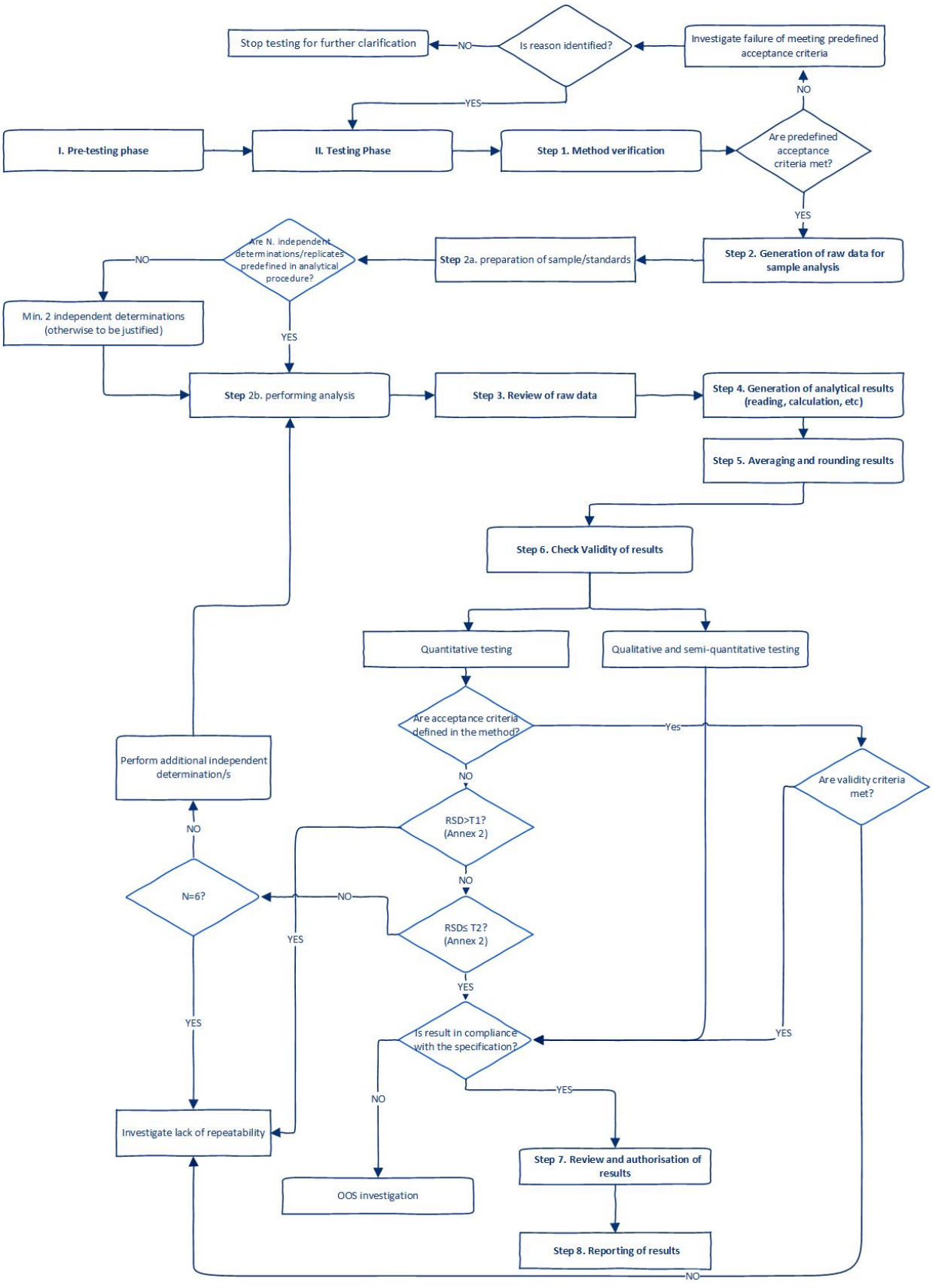
All testing activities in OMCLs shall be performed by qualified personnel, using suitable reference standards, calibrated/qualified equipment and validated methods (in accordance with the Guideline Validation/verification of analytical procedures) [2].

Compliance testing comprises testing towards previously defined specification limits using official and/or properly validated methods (e.g. compendial methods, methods described in the marketing authorisation holder (MAH) documentation or in-house developed methods). In compliance testing using compendial methods or methods described in the MAH documentation, the testing results shall be obtained by following the described analytical procedure and reporting instructions, ensuring that system suitability criteria are fulfilled.

For other testing activities (e.g. screening, analysis of unknown products, trace analysis) the suitability of the methods used shall be confirmed and documented (in accordance with the Guideline Validation/verification of analytical procedures) [2].

In order to assure the validity of testing results, generation and treatment of data obtained from analytical testing should follow the steps specified in the decision tree below for initial testing (Figure 1).

Figure 1. Initial testing decision tree



4.1.1 Pre-testing phase

This phase includes verification of the conditions for generating valid testing results, for example, confirming the existence of predefined acceptance criteria (inherent in the analytical method and/or internally established), verification of the method parameters and status of validation of the method, and availability of resources (i.e. qualification of personnel/equipment).

4.1.2. Testing phase

4.1.2.1. Method verification

The first step of the testing phase includes generation of raw data for method verification, encompassing set-up of the instrument, preparation of the solution(s) for system suitability testing and verification of the method, i.e. fulfilment of system suitability testing and internal acceptance criteria. System suitability testing, as an integral part of analytical procedures, is essential for verification of the method and includes evaluation of actual testing conditions (for example, equipment, analytical operations, analysed samples) according to predefined acceptance criteria. The predefined acceptance criteria may be described in the testing method or defined in the laboratory for internal quality control of the results.

A) Acceptance criteria described in the testing method

Testing methods described in pharmacopoeias or in MAH documentation describe system suitability criteria, which define method transfer and quality control requirements. Examples of system suitability criteria for HPLC methods include: number of theoretical plates, resolution, peak symmetry, instrument precision and method sensitivity (i.e. signal-to-noise ratio). Standard preparation accuracy using the comparison between the response factors obtained for two independent standard solutions (independent weighing) is usually described as a quality control requirement.

For compliance testing, the system suitability criteria defined in the analytical method shall be fulfilled, unless a scientifically sound and documented justification allows deviation of parameter(s) which do not influence method performance and validity of final results.

In some cases, whenever the acceptance criteria are not met, the laboratory shall investigate the cause. Depending on the outcome of the investigation, the testing can be resumed or stopped for further clarification e.g. with the Competent Authority.

Examples
(1.) HPLC method: the requirement for the resolution between two defined peaks in a liquid chromatography method for determination of the content of active substance is minimum 5.0. The testing is performed by following the described analytical procedure and the chromatographic conditions are adjusted, according to Ph. Eur. 2.2.46 requirements [10], but the maximum resolution value obtained is 4.8. In this case, deviation of acceptance criteria may be accepted, based on a documented scientific assessment on the impact of this deviation on the quality of the analytical result.

(2.) Cell culture: system suitability criteria may be highly dependent on the equipment used (with an impact on the sensitivity of the equipment), e.g. absolute values for the maximum and

minimum signal corresponding to maximum cell growth and maximum cell death in a bioassay. Therefore, when an OMCL is performing such test with the same type of equipment described in the protocol (but not exactly the same brand or model), the absolute values for the maximum and minimum signal may not be complaints.
In cell-based assays, characterised by multiple-dilution results analysed by, for example, parallel-line or 4-PL models, assay validity criteria are often highly dependent on the performance of the cell line, which can be affected by a number of different factors (e.g. medium composition, cell passage, incubators used). The minimum expected value for the coefficient of correlation or coefficient of determination may then be difficult to achieve. Further statistical elements, such as the linearity and parallelism of regression lines as well as the width of the 95% confidence interval of the potency estimate may be used as means to assess the validity of the assay results.

B) Acceptance criteria defined by the laboratory

Regardless of the analytical method acceptance criteria, the laboratory should define quality control requirements which complement the analytical method acceptance criteria and safeguard the quality of the test being performed. For example:

- criteria for method verification parameters (precision, linearity, accuracy);
- assessment of the blank;
- precision between sample preparations obtained by weighing independent amounts;
- recovery tests;
- control charts for assays used routinely (e.g. in OCABR).

For other testing activities (e.g. screening, analysis of unknown products, trace analysis) the suitability of the methods used shall be confirmed and documented (in accordance with the Guideline Validation/verification of analytical procedures) [2]. For quantitative testing, uncertainty of the measurement shall be evaluated and, when appropriate, the laboratory shall document the decision rule employed. Examples of how to evaluate the uncertainty of measurement are given in OMCL Guideline Evaluation of measurement uncertainty [3].

4.1.2.2. Generation of raw data for sample analysis

The second step of the testing phase includes generation of raw data for sample analysis, for example, preparation of the solutions (reference solutions/sample solutions) and performing the analysis (e.g. running the sequence in the appropriate order), following the described analytical procedure.

The reportable result should be based on a number of independent determinations, obtained from a number of observations (e.g. readings or injections), predefined in the test protocol and evaluated according to the instructions given in the described analytical procedure, which may be supplemented by internal procedures and criteria as appropriate. The test method/internal procedures should predefine the number of independent determinations/replicates, the modes of combination/calculation and validation criteria to be confirmed before a result can be either reported or (in the case of an OOS result) shall be confirmed by failure investigation, a retest programme and pooling of all valid reportable results in line with this guideline.

In cases where the analytical procedure does not define the exact number of independent determinations and the procedure for evaluation of results, or if compliance testing is performed

using in-house developed methods of analysis, the laboratory has to define and justify the number of independent determinations, depending on the method validation (if available), type of testing (qualitative or quantitative) and knowledge of the uncertainty contributors.

In certain cases e.g. screening methods, the laboratory may decide the number of independent determinations regardless the licensed method.

For practical reasons, the operational activities described in steps 1 and 2 of the testing phase can be combined (e.g. in one test run).

4.1.2.3. Review of the raw data

This step includes evaluation of the correctness of the measurements, integration parameters and resulting peak areas (for LC), transcription of input data (e.g. weighing, peak area, number of colonies).

4.1.2.4. Calculation of the results

Calculation of the results can be performed using manual calculators or a validated computerised system, including excel spreadsheets according to the Guideline Validation of computerised systems [4].

Where applicable, evaluation of measurement uncertainty should be performed according to the Guideline Evaluation of measurement uncertainty [3].

4.1.2.5. Averaging and Rounding of the results:

Averaging of the results must be performed according to the instructions specified in the test method. If averaging of the results is not specified in the testing method, the OMCL should clearly define how averaging of results is performed.

Averaging of the data depends on the sample and the method used.

Examples
In the potentiometric determination of pH value, the reportable result is determined by calculating the average of a number (for example 3) of measurements of a sample, and this average is reported as the test result.

For an HPLC method for assay of active substance, one independent determination has been carried out by three consecutive injections (replicates) of the same sample preparation. The reportable result is determined by averaging the peak responses from these replicates obtained from the same preparation. The assay result is calculated using the peak response average. This determination is considered as one test and one reportable result, and should fulfil the predefined acceptable precision criteria, e.g. based on validation criteria.

In cases of multiple independent determinations, where one reportable result is required by the method, for example assay of active substance, the average of these multiple assays is considered as one test and represents one reportable result.

Examples
For an HPLC method for assay of active substance, 3 independent determinations are performed (2 replicates (injections) for each independent sample preparation). The reportable result is determined by first calculating the arithmetic mean of the 2 replicates (injections); this mean is used to determine the results of samples 1, 2 and 3, respectively (three independent results), and to calculate the arithmetic mean of these three independent results.
For biological assays and tests in statistical assay layout, averaging and pooling of results is described in Ph. Eur. 5.3 [10].

For example, microbiological enumeration test Ph. Eur. 2.6.12. [10] the number of CFU per gram or per millilitre of product is calculated from the arithmetic mean of the counts per culture medium.
When evaluating results of microbiological contamination tests it is important to note that the contamination may not be distributed evenly throughout a product batch or sample. Homogeneity of a microbiological sample, for example, by thorough mixing prior to testing, does not imply a constant level of microbial cells throughout test sample units. Where the contamination is not uniformly distributed throughout a product batch or sample, i.e. contamination is detected in some but not all of the units, it may not be valid to pool and then average the count results from multiple units of the sample as this could average out a non-compliant result to a compliant result.

The rounding should be performed on the final calculated result only, in relation to the relevant decimal places or significant figures. The approaches for rounding the testing result to significant figures with practical examples are described in Annex 1. Rounding/significant figures.

4.1.2.6. Checking validity of results

For quantitative results (i.e. generated numerical values, regardless the format of the specifications), the laboratory shall evaluate the obtained results against predefined acceptance criteria (for example including repeatability/variability between replicated results for quantitative testing) according to the method (MAH dossier or Pharmacopoeia) or internal written procedures. The term "repeatability" may include additional sources of variability (e.g. different days) depending on the procedure applied. Approaches for evaluation of the results from quantitative testing based on the known variability of the method or based on statistical layouts are described in Annex 2.

This step is not applicable whenever acceptance criteria and actions to be taken are defined in the applied Ph. Eur. Chapters (e.g. dissolution test, disintegration, uniformity of dosage units).

This step is also not applicable for qualitative and semi-quantitative testing (comparative methods) where variability cannot be estimated.

4.2 Ensuring validity of testing results (including monitoring and trending)

According to ISO/IEC 17025:2017 clause 7.7, laboratories shall plan and perform documented activities to ensure the validity of the testing results, taking into account the risks associated with different testing activities of the laboratory. The data obtained from these surveys should be analysed and, where applicable, statistically processed and should be presented in a comprehensive way, allowing identification of the trend and monitoring of the validity of the results. The obtained results should be evaluated using justified quality control criteria (e.g. using control charts, certified reference materials, retained test samples) and used for making a decision

to undertake measures. The quality control criteria should be defined taking into account the measurement uncertainty of the results from these activities (evaluated according to OMCL Guideline Evaluation of measurement uncertainty) and the level of risk of the decision rule employed [3].

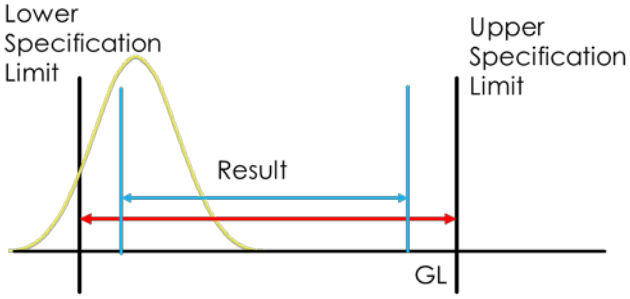
Participation in Proficiency Testing Schemes is an essential part of ensuring the validity of test results, as it involves comparison of the results obtained by the laboratory with results obtained by other laboratories and requires a continuous assessment of the performance achieved.

4.3 Decision rules (as defined in ISO / IEC 17025:2017)

For quantitative testing using compendial methods and methods described in MAH documentation, no further tolerances are to be applied to the limits prescribed to determine whether the sample being examined complies with the requirements of the monograph (e.g. if the limits are 95.0 – 105.0 %, they shall be used as such and shall not be modified based on estimated measurement uncertainty). These limits are based on data obtained in routine analytical practice and they take account of normal analytical errors, acceptable variations in manufacturing and compounding and deterioration to an extent considered acceptable [10]. The laboratory may decide in which cases the uncertainty of measurement will be estimated and taken into account in the statement of conformity to a specification limit.

In the case of in-house developed methods of analysis used in compliance testing, for other testing activities (e.g. quantitative testing for screening purposes, analysis of unknown products) or for confirmation of OOS results (e.g. in cases where the test could not be repeated), the decision rule describing how measurement of uncertainty is taken into account when stating conformity to specification shall be applied and documented, taking into account the level of risk of the decision rule employed, and therefore the level of risk of making a wrong decision.

An example of application of a decision rule for stating conformity to specification limits is given in Figure 2. The establishment of acceptance and rejection zones is based on the minimum acceptable level of probability that the result lies within the specification limits. In this example, the guard limit is calculated by using the value of expanded uncertainty of measurement, U, for k=2, for 95% level of confidence (lower specification limit + U and upper specification limit - U). Results falling outside of the guard limits are considered as out of specification.



GL=Guard Limit (additional limit, includes uncertainty of measurement)

Figure 2. Decision rule for conformity assessment (example taken from Eurolab technical report "Decision rules applied to conformity assessment" (2017))

More detailed explanations on choosing guard limits are given in the Eurachem/CITAC Guide "Use of uncertainty information in compliance assessment" [11] and the Eurolab technical report "Decision rules applied to conformity assessment" [12].

4.4 Out-of-specification (OOS) results

4.4.1 Failure investigation of OOS results

When a reportable result does not comply with the specifications ("suspected OOS"), the laboratory shall clearly define responsibilities and actions regarding the detection of OOS results, documentation, communication between the staff involved, failure investigation of results, assessment of root causes, approval of retesting plans, definition of corrections/corrective actions and closing of reports.

The OMCL should follow a standard procedure to establish whether this result is due to analytical error, and therefore not related to the quality of the product, or whether this result reflects the actual quality of the product tested. Information on how to manage OOS results is provided in Annex 3. Verification of Initial Out-of-Specification (OOS) results.

Statistical analysis for outlier test results can be included in the OOS investigation. The outlier testing should be performed using a statistical procedure for identifying extreme values, according to a written procedure, and properly documented. According to the Ph. Eur., the arbitrary rejection or retention of an apparently aberrant response can be a serious source of bias, and in general the rejection of observations solely because a test for outliers is significant is discouraged [10]. If justified, for biological assays with high variability of results, an outlier test may be appropriate to identify the statistically extreme results, which may be omitted from calculation of the reportable result. For validated chemical tests with relatively small variability, considering that a sample is homogeneous, outlier testing is based on a statistical analysis of the data obtained from testing and retesting and it cannot be used to invalidate (excluded) a suspect result. However, along with all other data from the investigation, it may help when evaluating the significance of the result.

Non-conformities detected during the failure investigation should be managed according to the quality management system in place, as appropriate.

The exact cause of an OOS result by the OMCL can often be difficult to identify. In addition to the other activities, the OMCL (or the Competent Authority that gives the order to test the medicinal product) may decide to review information from the manufacturer on the production and control of the suspect batch during the investigation phase.

4.4.2 Retest programme for confirmation of OOS results

If the suspected OOS result cannot be explained by a non-conformity detected during failure investigation, it is considered as an "initial OOS result" and the OMCL has to perform a retest programme to confirm the OOS result. In such cases, the numbers of replicates and operators, sampling procedure and the method for evaluating the results have to be predefined and documented following a standard operating procedure and/or specific instructions applicable to the individual case. The OMCL may decide on alternative analytical approaches, as long as it is able to demonstrate their validity for confirmatory testing.

If the retest programme is defined in the Ph. Eur. (e.g. repetition of the rabbit pyrogen test), that retest programme should be followed. The exact design of the retesting programme, in terms of conditions for repeating the test and evaluating the results, is generally not described in the MAH dossier.

Depending on the type of activity, specific documents may be available that define the different steps of the investigation and actions to be taken in cases where OOS results are obtained (e.g. in the CAP programme, document PA/PH/CAP (16) 103 R3 "Testing of Centrally Authorised Products (CAPs): Handling of out of specification (OOS) results") [13].

The retest programme and its evaluation should be based on sound scientific judgement and may depend on the characteristics of the test. Several examples of approaches for a retest programme are given in Annex 3.1. General Introduction - Verification of Initial Out-of-Specification (OOS) results by retesting, Annex 3.2. Verification of OOS results in quantitative testing, Annex 3.3. Verification of OOS results in qualitative testing and Annex 3.4. Special considerations from animal testing in connection with verification of OOS results. These examples are not mandatory and other approaches are possible; however, the scientific basis for decisions should be documented.

The mandatory basic principles of this core document are the following:

- Unless proven to be invalid, the initial OOS result shall not be rejected, but shall be included in the evaluation of the product, as for all other valid results.
- All retests shall be performed independently of each other, starting from the sample preparation.
- The maximum number of retests shall be predefined and limited and shall not be defined so as to "test a product into compliance". The results shall give a basis for the estimation of measurement uncertainty if this is not known from available validation data (preferably in-house, alternatively from the MAH dossier).

4.5 Review and authorisation of testing results

All reported results must be reviewed and authorised prior to release. Responsibilities for reviewing and authorising the release of results should be clearly defined.

The laboratory should ensure that all results subjected to review are obtained using detailed technical records, subjected to independent checks and to which statistical techniques are applied, where applicable. Review and authorisation of testing results prior to their release shall be performed by authorised personnel. It must be noted that the revised ISO/IEC 17025:2017 allows flexibility: in particular in the case of a small laboratory, reporting, review and authorisation may be carried out by the same person. However, in such cases it is recommended to provide appropriate explanatory documentation.

Where electronic data review and authorisation is implemented, data integrity should be ensured according to the Guideline Validation of computerised systems [4].

5. Reporting of results

The results obtained from testing shall be provided in a test report fulfilling the requirements stated in clause 7.8 of ISO/IEC 17025:2017. The OMCL may report the results differently, provided

that there is a documented agreement with the customer considering the requirements of ISO/IEC 17025:2017 (clause 7.8) [1].

Testing results may be presented as values and their units of measurement, or using descriptions (conforms/does not conform to specification requirements). For compliance testing, the results presented as numerical values should be reported in accordance with the instructions in the analytical method (as the mean of all valid results), given with the same number of decimal places as the specification limits.

In cases when the uncertainty of measurement is relevant to the validity of the test result or affects the conformity to a specification limit, or when it is required by the customer, the result shall be reported together with the value of measurement uncertainty (as described in the Guideline Evaluation of measurement uncertainty) [3]. If the statement of conformity to a specification is based on a decision rule, information about the applied decision rule shall be reported.

For other testing activities, results presented as numerical values should be reported as the mean of all valid results, given with the same number of decimal places as the specification limits or rounded to the number of significant figures defined by the laboratory, together with the value of measurement uncertainty (as described in the Guideline Evaluation of measurement uncertainty). If a statement of conformity to a specification is included, information about the applied decision rule shall be reported.

In terms of reporting formats, the data obtained should always be reported in the same format (i.e. number of decimal places) as in monographs or specifications. An exception, as required by ICHQ3A, is applied for impurities below 1.0%; in this case the limit is quoted to 1 decimal place but the results should be reported with 2 decimal places [14].

If a product does not comply with the specification, a critical evaluation shall be made, taking into consideration relevant information from the manufacturer, if applicable. A recommendation to the Competent Authority for follow-up activities may be included in the report.

However, where specific procedures already exist for the reporting of results (e.g. OCABR – EC Administrative procedure for Official Control Authority Batch Release, PA/PH/OMCL (19) 138 DEF), these shall be followed and any sharing of information with other organisations shall respect the confidentiality requirements of that activity (e.g. EU-specific networks versus general OMCL activities). In addition, the OMCLs and Competent Authorities involved should define their in-house procedures for storage and internal exchange of data and any follow-up measures, taking into account the recommendations described above.

In the context of OCABR testing, conformity is externally reported to the applicant in the certificate (format described in Annexes I1a-g of the administrative procedure for OCABR).

For internal reporting of test results to the signatory of OCABR certificates (the customer of the testing activities), the results may be reported in simplified form (e.g. by direct access to the LIMS). The "agreement with the customer" for simplified reporting required by ISO 17025, 7.8.1.3 shall be documented, e.g. in a quality system document.

6. References

(For all references, the latest version applies)

1. ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories”
2. OMCL Guideline “Validation/Verification of analytical procedures”
3. OMCL Guideline “Evaluation of measurement uncertainty”
4. OMCL Guideline “Validation of computerised systems”
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14. Q3A Impurities in new drug substances, ICH Harmonised tripartite Guideline.