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DECISION RULE – STATE OF CONFORMITY

General

1. Any decision rule and any state of conformity declared, is done based on the result and the measurement uncertainty.
2. When the measurement result (a) is evaluated according to a specification, standard or requirement and in any case of a specified legislated maximum limit, L_{max}, using **U=2*u** (where **U** is the Expanded Uncertainty determined with a coverage factor **k=2** for confidence interval equal to 95% and **u** is the combined standard uncertainty), then this is:
   - Considered as **non-compliant** for confidence interval 95% when:
     a-U>L_{max}
     a+U<L_{min}

   - Considered as **compliant** for confidence interval 95% when:
     a-**U≤L_{max}**
     a+U≥L_{min}

Where:
A = the measurement result
U= the expanded uncertainty of the measurement (for confidence interval equal to 95%)
L_{max} = maximum limit of a legislation or a specification
L_{min} = minimum limit of a legislation or a specification

3. When the measurement result (a) is evaluated according to a specific value L, then the sample is considered as:
   - **Non-compliant** when the value L is beyond the range a ± U
   - **Compliant** for confidence interval 95% when a – U ≤ L ≤ a + U

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Decision rule for Preservation Efficacy Test according to ISO 11930

According to ISO 11930 (§ 5.7.1), the decision rule applied by the laboratory accounts for the inherent variability of the method. A deviation of up to 0.5 log units from the predefined acceptance criteria (A or B) is considered acceptable for each microorganism at each time point, provided that the calculated expanded uncertainty is below 0.5 log.

Statement on Certificates:

“Meet the relevant A/ B criterion.

The inherent variability in microbial counts that are used to determine Log reduction values per interim, shall be taken into consideration when comparing with the preset criteria A or B. In this study results interpretation, a deviation of 0.5 log units from the preset criteria is considered acceptable, according to ISO 11930 - 5.7 Interpretation of test results and conclusions.”

Decision rule for Preservation Efficacy Test according to Eur. Pharmacopoeia 5.1.3

The decision rule applied by the laboratory for the Preservation Efficacy Test, according to the European Pharmacopoeia 5.1.3 method, specifies that the required microbial reductions, expressed in log units for each microorganism at each time point, must strictly meet the defined acceptance criteria of the method, based on their absolute integer values, exactly as stated in the standard, without applying any additional variability margins.

Statement on Certificates:

"Meet the relevant A criterion”/ “Meet the relevant B criterion”.

Decision rule: The microbial population reductions, expressed in Log units, must strictly meet the method’s predefined acceptance criteria as absolute values, without additional variability margins. This approach ensures compliance with the standard’s requirements, considering method’s calculated expanded uncertainty (<0.5 log).

Decision Rule for Microbiological Testing of Cosmetics According to Eur. Pharmacopoeia 5.1.4 and ISO 17516

The decision rule for evaluating microbiological results according to Eur. Pharmacopoeia 5.1.4 and ISO 17516 is based on adapted acceptance limits that take into account the inherent variability of microbiological analysis methods. Specifically, due to the inherent variability of plate count methods, and in accordance with ISO 17516 and Eur. Pharmacopoeia 2.6.12, results are interpreted as non-compliant if they exceed the following thresholds:

a) > 20 CFU/g or ml, when the acceptance criterion is ≤10 CFU/g or ml
b) > 200 CFU/g or ml, when the acceptance criterion is ≤100 CFU/g or ml
c) > 2000 CFU/g or ml, when the acceptance criterion is ≤1000 CFU/g or ml.

This approach is explicitly described in both referenced methods and aligns with international practice for interpreting microbiological data.

Statement on Certificates:

1. Within limits: when no recovery above the detection limit is observed for any of the tested parameters.
2. Out of limits: when recovery above the acceptance limit is observed for at least one tested parameter, taking into account the inherent variability of the method as described above.
3. Within limits according to criteria, provided that the microbiological risk is controlled and assessed in accordance with ISO 11930 or ISO 29621 (i.e., no potential for microbial proliferation in the product)," or no comment is included (in the case of pharmaceuticals), if microbial growth is observed but remains within acceptable limits.