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ISP incorporates new strains of *Burkholderia spp.* into suitability requirements of microbiological methods for pharma products

MINSAL publishes ISP Resolution on the incorporation of new strains of Burkholderia spp. into the requirement for demonstrating the suitability of microbiological methods in sterility and pathogen absence tests for pharmaceutical products

On December 19, the Ministry of Health (MINSAL) published in the Official Gazette the Exempt Resolution Number E 2.854/24 of the Public Health Institute (ISP), which mandates the incorporation of new strains into the requirement for demonstrating the suitability of microbiological methods in sterility and pathogen absence tests for sterile pharmaceutical products.

The resolution refers to point 3.1 of Technical Standard No. 180, on Good Laboratory Practices for Pharmaceutical Microbiology Laboratories, which states: "*Standard (pharmacopoeial) test methods are considered validated. However, it is necessary to demonstrate that the specific test method to be used by a given laboratory for the analysis of a given product is suitable for use in the recovery of bacteria, yeasts, and filamentous fungi in the presence of the specific product.*

The laboratory must demonstrate that the performance criteria of the standard test method can be met by the laboratory before introducing the test as a routine test and that the specific test method for a given product is suitable. including positive and negative controls".

Therefore, it is necessary to require the demonstration of the suitability of microbiological methods to ensure that the obtained result represents the true estimation of the microbial population present in the sample, without the possibility of false negatives being disregarded.

The resolution establishes the mandatory incorporation of the *Burkholderia* complex in the suitability tests of microbiological methods for the sterility testing of sterile pharmaceutical products, corresponding to the following strains:

1. *Burkholderia cepacia* ATCC 25416, NCTC 10743 o CIP 80.24.
2. *Burkholderia cenocepacia* ATCC BAA-245 o LMG 16656.
3. *Burkholderia multivorans* ATCC BAA-247, LMG 13010, CCUG 34080, CIP105495, DSM 13243 o NCTC13007.

Quality control laboratories will have a period of **12 months** from the publication of this resolution to implement the new strains into the requirement for demonstrating method suitability, that is, until **December 19, 2025**.

The specific obligation of compliance with this resolution falls on quality control laboratories, but the marketing authorization holders are not exempt from fulfilling their quality obligations.

Holders must always ensure that the facilities authorized in their respective marketing authorizations, which carry out quality control, have the necessary method suitability for the analysis of their products.

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