

# MICROBIOLOGICAL REFERENCE MATERIALS

## *Burkholderia cepacia* complex (Bcc)



### EXPERIENCE

**ielab** is a company belonging to SUEZ group that has a wide experience providing services and products related to the application of quality in laboratories. Our main products are **Reference Materials**, including **Accredited Reference Materials** according to ISO 17034 (BACredi), and **Proficiency Test Schemes accredited** according to ISO 17043.

### *Burkholderia cepacia*

Contamination by microorganisms of the *Burkholderia cepacia* (Bcc) complex has been responsible in the last years for the recall of most non-sterile pharmaceutical products.

The **complex Bcc** include a group antibiotics and antimicrobial agents resistant bacteria that are capable of causing opportunistic infections in immunocompromised people.

In December 2019, the USP published the new chapter **USP<60> "Microbiological examination of non-sterile products-Test for *Burkholderia cepacia* complex"** where the test methods to determine the absence of Bcc in water, raw materials and non-sterile pharmaceutical products are described.

### REFERENCE MATERIALS

**ielab** offers quantitative **Microbiological Reference Materials**, presented in tablet format, for the different strains indicated in the **USP<60>**:

- *Burkholderia cepacia* ATCC 25416
- *Burkholderia cenocepacia* ATCC BAA-245
- *Burkholderia multivorans* ATCC BAA-247
- *Pseudomonas aeruginosa* ATCC 9027

The USP<60> recommends carry out both Growth Promotion (GP) and Suitability test, thus these **Reference Materials** are presented in two different **concentration ranges**:

- ❖ Low range: <100 cfu/0.1mL
- ❖ Extra high range: 10<sup>7</sup>-10<sup>8</sup> cfu/tablet (10<sup>5</sup>-10<sup>6</sup> cfu/0.1mL)

### "IN HOUSE" STRAINS

If any company detects any positive of *Burkholderia* in its facilities or products, should isolate, identify and conserve the strain to include it in future tests.

Thus, **ielab** offers to the pharmaceutical, para-pharmaceuticals and cosmetic companies the service for manufacturing **Reference Materials** from their own strains or isolated strains obtained in their facilities. **ielab** offers also an identification service by sequencing for the "in house" isolated strains.



## PHARMACOPOEIA

**ielab** offers quantitative **Microbiological Reference Materials**, presented in tablet format, for the different strains indicated in the **European Pharmacopoeia**:

- *Escherichia coli* ATCC 8739
- *Clostridium sporogenes* ATCC 11437 y ATCC 19404
- *Pseudomonas aeruginosa* ATCC 9027
- *Staphylococcus aureus* ATCC 6538
- *Bacillus subtilis* ATCC 6633
- *Bacillus cereus* ATCC 11778
- *Candida albicans* ATCC 10231
- *Aspergillus brasiliensis* ATCC 16404
- *Salmonella* spp. serovar *Abony* NCTC 6017
- *Salmonella* spp. serovar *Typhimurium* ATCC 14028

This materials are available in three **different concentration ranges**:

- ❖ Low range: <100 cfu/0.1mL
- ❖ High range: >100 cfu/0.1mL
- ❖ Extra high range:  $10^7$ - $10^8$  cfu/tablet  
( $10^5$ - $10^6$  cfu/0.1mL)

## BACuanti



## OTHER SERVICES

In **ielab** we are at the service of our clients and their needs, do not hesitate to contact us for any project or activity in which we can be useful to you, beyond our catalogue products such as:

- Organization of inter-laboratory tests
- Internal quality controls
- Hazard Analysis and Critical Control Points (HACCP)
- Validation of cleaning or sterilization processes

If you need more information please, do not hesitate to contact us at the e-mail address [comercial@ielab.es](mailto:comercial@ielab.es), we will be glad to assist you.

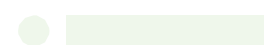
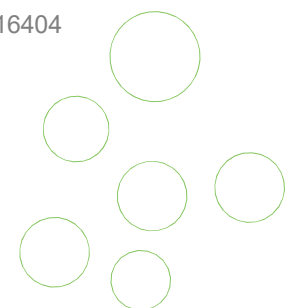
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## DOBLE CUANTIFICACION

**ielab** offers **References Materials** quantified (<100 cfu) by means of 0.1 mL spread plate method, both in general culture medium and in the specific culture medium indicated by the **European Pharmacopoeia** in **section 2.6.13**, for each of the following microorganisms:

- *Escherichia coli* ATCC 8739
- *Clostridium sporogenes* ATCC 11437 y ATCC 19404
- *Pseudomonas aeruginosa* ATCC 9027
- *Staphylococcus aureus* ATCC 6538
- *Salmonella* spp. serovar *Abony* NCTC 6017
- *Salmonella* spp. serovar *Typhimurium* ATCC 14028
- *Aspergillus brasiliensis* ATCC 16404
- *Bacillus subtilis* ATCC 6633
- *Candida albicans* ATCC 10231

## BAControl



[www.ielab.es](http://www.ielab.es)