

## Microbiological Testing of Cannabis Products

Reliable, reproducible, easy testing

Why wait days to get results?

The GeneDisc Rapid Microbiology System helps to provide microbial test data in as little as two hours, using a simple, robust and cost-effective platform based on quantitative Polymerase Chain Reaction (qPCR) technology. The GeneDisc Systems is an attractive alternative to existing microbiological test methods.

### GeneDisc System Benefits

**Rapid** — While culture methods require up to 12 days to obtain results, Pall's GeneDisc method allows a specific detection in less than 24 hours.

**Unambiguous** — The PCR specificity allows a direct and accurate identification of key microorganisms.

**Easy to use** — Pall GeneDisc method makes the PCR easy for everyone. Matrix specific protocols are designed for routine use and validated from sample to result, with a straightforward workflow.

**Modular** — System modularity is flexible based on your throughput requirements: up to 48 samples for detection and identification can be simultaneously analyzed.

**IQ OQ Service** — Documentation is available supporting regulatory requirements for testing method compliance.

### All Key Bacteria in One Test

The GeneDisc Plate for Specified Microorganisms enables rapid and simple assays for the key indicator microorganisms used in a compendial test, such as the new harmonized Microbial Limits Test (USP <62>).

Each plate contains six sectors, with six wells per sector. Each of the six wells contains reagents to detect one or more microbial targets simultaneously. An entire sector of six wells provides data for six different microorganisms (see below) plus an internal positive control. This novel assay design maximizes data for a single sample. Six samples can be tested per plate.

Indicator organisms are:

- *Escherichia coli*
- *Salmonella* spp.
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Candida albicans*
- *Burkholderia cepacia* complex

Testing methods for all other key food-borne pathogens, such as *Salmonella* and *Listeria*, as well as pathogenic strains of *Escherichia coli*. are also available.

**For more information, visit us on the web at [www.pall.com/genedisc](http://www.pall.com/genedisc).**



## Specified Microorganisms

### Acceptance Criteria for Microbial Quality of Nonsterile Dosage Forms

Route of Administration	Specified Microorganism(s)
Nonaqueous preparations for oral use	Absence <i>E. coli</i> (1g or 1ml)
Aqueous preparations for oral use	Absence <i>E. coli</i> (1g or 1ml)
Oromucosal, Gingival, Cutaneous, Nasal, Auricular use	Absence <i>Staphylococcus aureus</i> (1g or 1ml) Absence <i>Pseudomonas aeruginosa</i> (1g or 1ml)
Vaginal use	Absence <i>Staphylococcus aureus</i> (1g or 1ml) Absence <i>Pseudomonas aeruginosa</i> (1g or 1ml)
Transdermal patches (limit of 1 patch including adhesive layer and backing)	Absence <i>Staphylococcus aureus</i> (1g or 1ml) Absence <i>Pseudomonas aeruginosa</i> (1g or 1ml)
Inhalation use	Absence <i>Staphylococcus aureus</i> (1g or 1ml) Absence <i>Pseudomonas aeruginosa</i> (1g or 1ml) Absence of bile-tolerant Gram-negative bacteria (1g or 1ml)



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