

USP <81> Antibiotic Testing



Figure 1: Results using Cylinder Plate Method antibiotic assay approach

Overview of Antibiotic Testing

Eurofins BioPharma Product Testing (BPT) is highly proficient in testing for antibiotic effectiveness by USP <81> Antibiotic – Microbial Assays. This general chapter covers microbial assays for determining antibiotic activity/potency, which covers 29 antibiotics.

Our GMP compliant Microbiology Lab offers comprehensive testing to determine the effectiveness of your specific antibiotic to inhibit the growth of targeted microorganisms.

Bacitracin, Tylosin, Neomycin and Polymyxin B are the most common antibiotics used in OTC consumer products. Consultation is available for development and validation of other antibiotics.

Benefits of choosing Eurofins BPT Toronto:

- ❖ Industry leading GMP lab with full capacity for testing antibiotic products by USP<81>
- ❖ Established testing in common product matrices including antibiotic ointments, creams, ophthalmic solutions, and feed additives
- ❖ R&D for suitability with a spectrum of product matrices and optimization of extraction protocols

There are 2 common techniques for determining antibiotic activity:

1. **Cylinder Plate Method** using a vertical cylinder
2. **Turbidimetric Assay** using a growth inhibition assay with liquid medium

All formulations require validation - Validation establishes a maximum value for the confidence interval width, which is then used in the calculation to estimate antibiotic potency.