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Comprehensive *In-Vitro* Microbial Kill Rate Studies for screening antimicrobial agents

Conducting *in vitro* time kill-rate studies with in-depth accuracy and precision is the most appropriate method for assessing the bactericidal or fungicidal impact of new or established drug candidates or other substances/materials, as well as for comprehending the dynamic relationship between antimicrobial agents and microbial strains. These studies also play an important role in evaluating the antibiotic component of combination products and to determine synergism or antagonism between drugs (two or more) in combinations.

Aragen Life sciences has established a dedicated, state-of-the-art lab for microbiological testing services equipped with all the modern equipment's. We can expertly perform a range of microbiological assessment tests and have expertise in performing *in vitro* time kill-rate studies of range of products, including pharmaceuticals.

Capabilities:

- Extensive comparison of antimicrobial property of Reference Listed Drug (RLD) vs Test product.
- Extensive bactericidal or fungicidal assessment in time and concentration dependent manner.
- Studies are conducted by using 12 replicates of each organism (18 organisms) as per USP<51> and indication section of RLD label.
- Dedicated laboratory equipped with all the modern equipment.
- Experienced microbiologists, well-trained in aseptic techniques and Good Laboratory Practices.
- Protocols for determining synergism or antagonism between drugs (two or more) in combinations.
- Well documentation and validated test reports with professional photography.

Role of Kill Rate Studies in the Regulatory Approval Process:

Early Development and Screening: Library of compounds are screened and prioritized based on their inhibition potential.

Dose Selection: Results from these studies enable the researchers to estimate optimal dosage required for therapeutic effect in vivo studies.

Comparative Analysis: Demonstrating the efficiency of the new drug, providing valuable information for regulatory agencies to make approval decisions.

Resistance Development: Understanding how quickly resistance may emerge can influence dosing strategies and treatment guidelines to minimize the risk of resistance.

Process outline:

Designing a comprehensive study plan and parameter optimization: Method development and validation and main study with RLD and test product.

Method Development: Planned with single trial 18 organisms with reference listed drug.

Method Validation: Planned with three trial 18 organisms with reference listed drug.

Main Study: Planned with 12 trials, 18 organisms with reference listed drug.

Experience that counts:

- Multiple studies have been conducted over the last 5 years.
- **Clientele** - Companies (Pharmaceutical, Lifesciences, Healthcare, Agrochem, Medical devices, Cosmetic), all across the globe.

To know more about our capabilities and to speak with our subject experts write to us at bd@aragen.com.

Let's begin the conversation

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