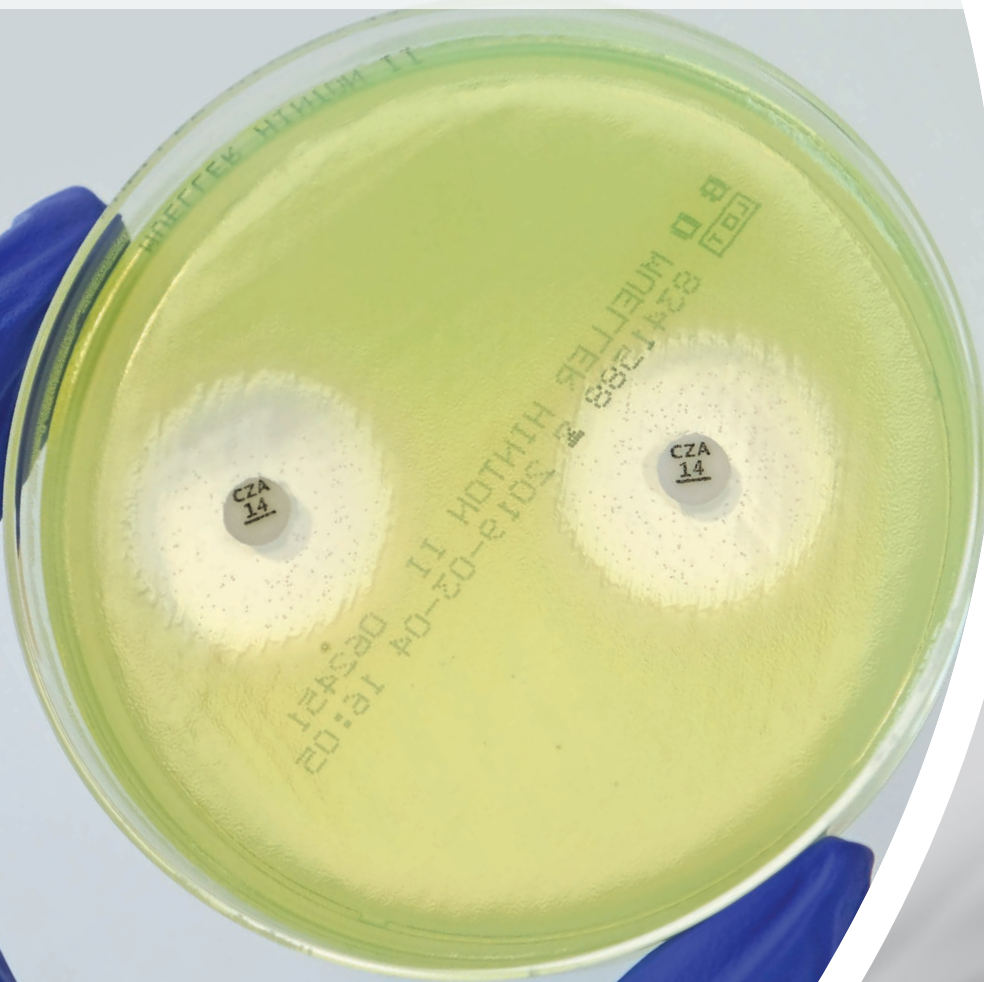




mastpharma[®]

Antimicrobial Susceptibility Test Development for the Pharmaceutical Industry



- Antimicrobial susceptibility test discs
- Real-time stability studies
- Clinical and veterinary compound studies
- Meets EUCAST and CLSI requirements

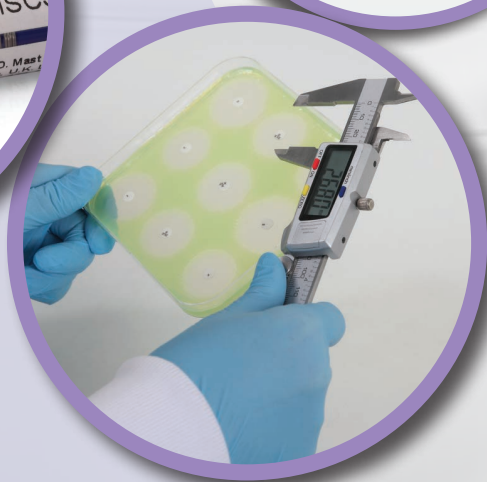
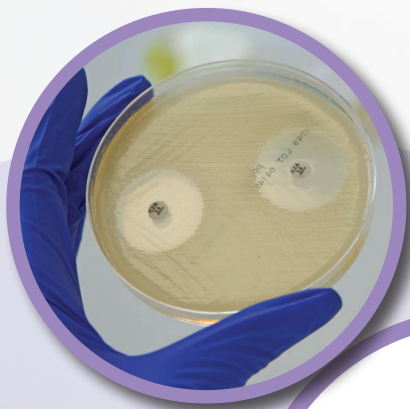


Mast Group Ltd offers a range of services including **mastpharma® development** and **mastpharma® stability** for the evaluation of novel antimicrobial compounds for the pharmaceutical industry.

Clinical trials of antimicrobials require the design of diagnostic devices to determine microorganism susceptibility before the compound enters Phase 3.

Antimicrobial susceptibility test discs are proven to be one of the most effective and validated methods to determine bacterial susceptibility in both clinical and veterinary practice, and must be commercially available at the launch of the compound to assure full market penetration.

Utilising its 60 years experience of development and manufacture of antimicrobial test products, **mastpharma®** offers extra confidence in the success of the antimicrobial on final commercialisation.



In the disc development phase an antimicrobial susceptibility test (AST) disc containing a novel compound is formulated. Additionally, methods for the assay of its content are verified. Initial stress studies identify the most suitable candidate formulation for production of stable, investigational use only (IUO) AST discs, preliminary QC criteria are generated during this process.



mastpharma[®]

stability

A minimum of three replicate batches of product are manufactured and entered into real-time stability studies. Studies carried out under both normal storage and additional stress conditions allow trending to be monitored and ensure final product retains effective performance for the duration of its allocated shelf life.



Services Available

Mast Group Ltd offers the following flexible and convenient services to provide pharmaceutical companies with confidence in quality, and assist with easy distribution and integration for market evaluations:

- Continuation of performance studies are available at 3, 6, 9 and 12 months on first batch manufacture.
- On compound approval by the FDA and EMA, CLSI and EUCAST disc versions are made available. Antibiotic discs are then launched and supplied as part of the **MASTDISCS®** stock range.
- Bespoke labelling available to customer's specification fulfillment programmes.
- Distribution to end users on behalf of pharmaceutical company.
- Multiple disc cartridge formats meet international requirements.



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