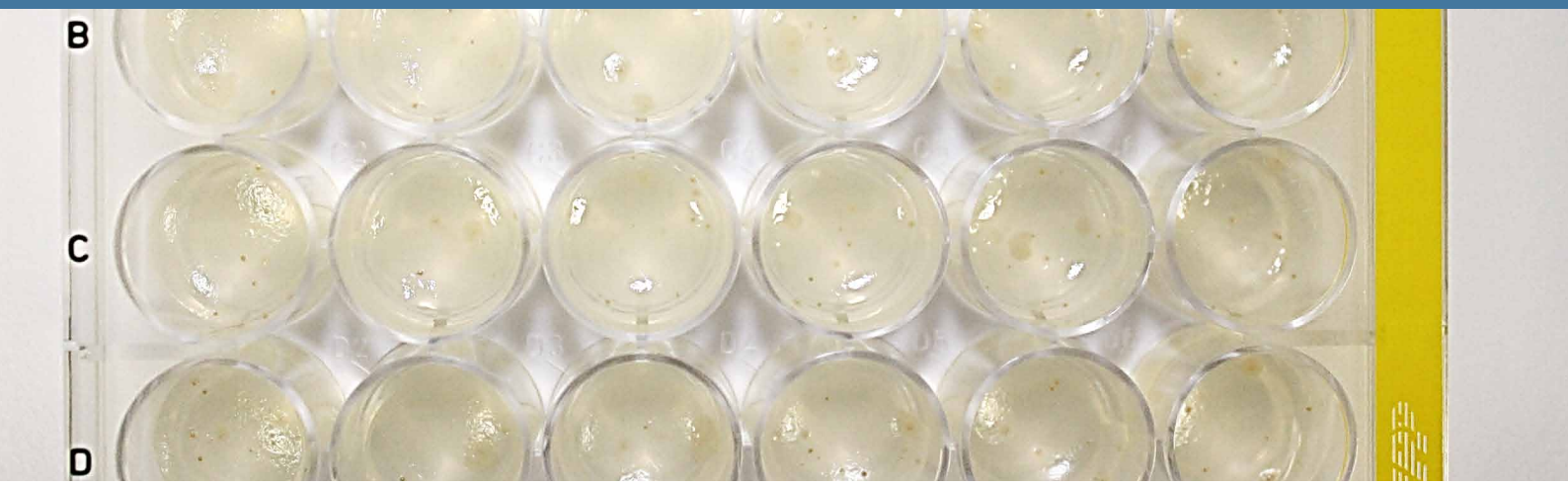
Genotoxicity screening for R&D

Micro-Ames: Bacterial Mutation Test



Early identification of genotoxic chemicals during development is crucial, to save time and resources.

Confarma offers the micro-Ames test, a genetic toxicology screening assay, to help identify the right chemical candidates at early stage of development. The micro-Ames test validated at Confarma, allows miniaturized and highly predictive screening of compounds in a 24-well plate format, saving test articles and time. Following ICH M7, the micro-Ames test also allows evaluation of mutagenicity of pharmaceutical impurities, and control of DNA reactive impurities in pharmaceuticals, to limit potential carcinogenic risk.

TESTING OF COMPOUNDS AND IMPURITIES FOR

- Pharmaceuticals
- Chemicals
- Cosmetics

ADVANTAGES OF MICRO-AMES

- Validated test method
- Highly predictive results compared to regulatory GLP studies and OECD guideline 471
- Save material: 20 times less material required
- Save time: high throughput (screening)
- Lower costs

HIGHLY PREDICTIVE RESULTS

- Same assay methodology as the standard plate method described in the OECD guideline 471
- Use of the five OCDE 471 strains: TA98, TA100, TA1535, TA1537 and uvrA pKM101
- Assay in presence and absence of metabolic activation S9
- Up to 8 dose levels tested.

LITERATURE

OECD guideline 471: Bacterial Reverse Mutation Test
ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

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