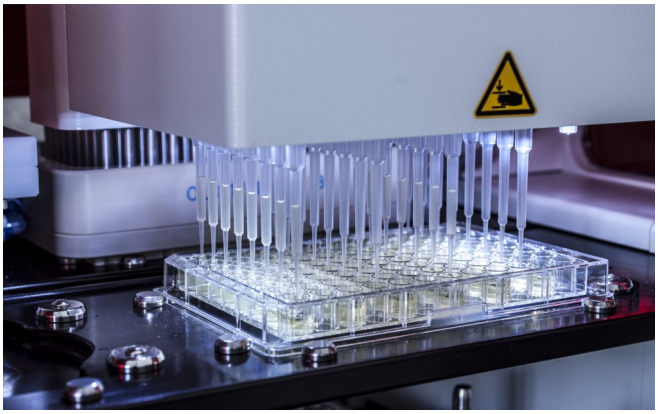
FADU assay

Safety testing on genotoxicity



Safety tests for chemicals (according to REACH), botanicals (THMP) and cosmetics

As part of the safety assessment of chemicals, botanicals (THMP) and cosmetics, the determination of possible genotoxic effects is a critical factor for product authorisation. Applying in vitro testing, a combination of tests is usually used to answer this complex question. A valuable element of this test setup is the automated detection of DNA strand breaks via FADU assay (as an alternative to the Comet assay).

High standardisation through automation

Since 2007, the EU REACH regulation commits manufacturers, importers, formulators and downstream distributors to ensure the reliable characterisation of all chemicals brought on to the general market. As an alternative or complement to the comet assay, BioTeSys provides a rapid test that is well-standardised thanks to the use of automated work processes: the FADU assay (fluorimetric detection of alkaline DNA unwinding). This process is also characterised by scalable incubation times (minimum incubation time 30 minutes). DNA damage can be determined directly after the removal of the genotoxic agent or even after a repair phase.

Screening with the highest result precision

Automation makes the assay a cost-effective and rapid screening procedure. The genotoxic properties of substances can be detected quickly and reliably–in a wider range and in more dilutions and mixtures. Early decision making in product development of pharmaceuticals and chemicals is significantly accelerated by this approach. Moreover, the obtained data can be used to support the submission of safety dossiers.

Significance

The FADU assay is a procedure for the direct detection of DNA strand breaks. The assay is compatible with chemicals, raw materials, extracts and nanoparticles.

The key advantages of the method:

- automated and thus well standardised
- high reproducibility
- high throughput with a pure analysis time of under three hours
- extremely sensitive
- inexpensive

Applicable cell models:

- suspension cultures
- adherent cells
- reconstructed human epidermis

Other established methods for genotoxicity detection at BioTeSys are the γ-H2A.X assay and micronucleus assay according to OECD TG 487.

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