



FADU ASSAY

Safety testing on genotoxicity

SAFETY TESTS FOR CHEMICALS, BOTANICALS 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. In addition to data from tests such as the Ames test, the comet assay or the micronucleus assay, our automated FADU assay offers our customers a cost-effective screening approach for the detection of DNA strand breaks. Due to its automated performance in a multi-well format, this assay is ideally suited for upstream screening approaches as well as for accompanying product controls.

HIGH STANDARDISATION THROUGH AUTOMATION

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 (fluorometric detection of alkaline DNA unwinding). This process is also characterised by scalable incubation times. DNA damage can be determined with and without metabolic activation 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 method, making it a valuable tool during product development. 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 well standardised
- high throughput (96-well format)
- highly reproducible
- highly sensitive
- pure analysis time of under three hours
- cost-effective

Applicable test models:

- suspension cultures (standard method)
- adherent cells representing different tissues

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