

BioPharma Product Testing







OECD 202: daphnia sp, acute immobilisation test - limit test and EC₅₀ - GLP

Application field

This test is applicable to readily and poorly soluble and volatile substance.

Interests

The purpose of this test is to determine acute toxicity effects of chemicals towards daphnies...

Principle of the test

Young daphnies, aged less than 24 hours at the start of the test, are exposed to the test substance at a concentration of 100 mg/l in the limit test, or at a range of five concentrations in the full study (EC50 test) for a period of 48 hours.

Normative references

OECD Guidelines for testing of Chemicals – Daphnia sp., Acute immobilisation test. N° 202 – 13/04/2004.

Restrictions

- For chemicals of low solubility in water, the maximum concentration should not exceed the limit of solubility in the dilution water.
- A reliable analytical method for the quantification of the test substance in the test solution must be available.



Expression of results

Limit test:

if immobilisation is > 10% a EC50 test should be conducted.

EC50 test:

data are analysed by appropriate statistical methods to calculate the EC50 with 95% confidence limits.

Number of products Quantity necessary to the analysis

Quantity on request with the following information:

- Name of the product
- Batch number
- Expiry data
- Storage and stability conditions
- Qualitative composition
- Quantitative composition
- · Certificate of analysis
- Water solubility
- pKa value
- n-Octanol/water partition coefficient

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