

## MT 41.1 DILUTION STABILITY OF AQUEOUS SOLUTIONS

### SCOPE

The purpose of this method is to identify potential sprayability issues for formulations forming an aqueous solution of active ingredient(s). In particular, this method should identify potential nozzle blockage or spray solution inhomogeneity issues.

### OUTLINE OF METHOD

A sample is diluted in water and allowed to stand for 24 hours after which the quantity and nature of any separated material is assessed.

### APPARATUS

*Measuring cylinder* 100 ml

*Water bath* capable of maintaining a specified temperature (Note 1)

### REAGENT

CIPAC Standard Water D (MT 18.1.4) unless otherwise specified

### PROCEDURE

Dilute the specified amount of the formulation, or if not specified 5 ml, to 100 ml with Standard Water and allow the solution to stand for 24 h at  $30\text{ }^{\circ}\text{C} \pm 2^{\circ}\text{C}$  (Note 1). Note if any material has separated after standing for 30 min and 24 h

If any material has separated after 24 h, then pour the test solution through a 75  $\mu\text{m}$  sieve according to a procedure adapted from MT 185 (b) *Wet sieving*. Determine the amount of residue and the content of the a.i. in this residue.

*Note 1* The temperature should be consistent with the use conditions of the product. Often  $30\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$  is readily maintained in a thermostat bath. In practice however, lower temperatures (e.g. ambient) may be more appropriate.