# MT "19X_Sol" Solution Stability of Water Soluble Tablets (ST)

## Scope

The method is intended for measuring the stability of solutions of water soluble tablets (ST).

## Outline of method

A water soluble tablet, or a fragment of a water soluble tablet, is dissolved in Standard water D at maximum use rate and stirred for a specified time. The solution is allowed to stand undisturbed for 2 hours and then poured onto a 75 µm sieve. Any residue is collected, dried, weighed and recorded.

## Reagents

*Standard water D*, MT 18.1.4, unless otherwise specified
*Water*, deionised

## Apparatus

*Beaker*, 1000 mL with a diameter of 102 ± 2 mm (short)
*Watchglass*
*Glass dish*
*Analytical balance,* with an accuracy of ± 0.1 mg
*Top loader balance*, with a capacity of at least 2 kg and an accuracy of ± 1 g
*Stirrer motor* with speed control
*Stainless steel stirrer propeller* type with four fixed stirrer blades set at an angle of 45 °, shaft length: 350 mm, propeller diameter: 50 mm, blade with: 10 mm (Note 1)
*Stopwatch*
*Thermometer*
*Sieves*, 75 µm, 100 mm diameter, ISO 565 (see also CIPAC F, page 178, table 1)
*Dryer*, with temperature control
*Desiccator*

## Procedure

Based on the measured weight of the tablet, or the tablet fragment, calculate the volume of Standard water D to give the maximum recommended use concentration (Note 2).
Weigh the mass of Standard water D which has previously been brought to a temperature of 25 ± 5 °C into the tared 1 l beaker. The stirrer should be centrally located in the beaker and is positioned in such a way that the bottom of the stirrer blades is 15 mm above the bottom of the beaker. The pitch of the stirrer blades and the direction of rotation are such that the propeller pushes the water upwards.
Switch on the stirrer with a speed set to 300 rpm. Add the tablet, or a tablet fragment of it, to the water and continue stirring for the time specified by the manufacturer (Note 3). Note the stirring time. Switch off and remove the stirrer, briefly rinse the stirrer (~ 10 mL) with Standard water D into the beaker, cover the beaker with a watchglass and allow to stand for 2 hours at 25 ± 5 °C.
After 2 h, transfer the contents of the beaker onto a 75 µm sieve. Collect the filtrate and rinse the beaker and the sieve with deionised water. Transfer the residue to a glass dish (a in [g]) with a jet of deionised water from a wash bottle. Dry to constant weight (Note 4) and record the weight of the glass dish (b in [g]). Calculate and report the residue for this sample (Note 5).

## Calculation

$$\text{Residue (R) after 2 hours} = \frac{(b - a) \times 100}{w} \ \%$$

where:

a = mass of the glass dish [g]
b = mass of the glass dish and residue [g]
w = mass of tablet/fragment added [g]

Note 1 For the stainless steel stirrer see also CIPAC handbook F, method MT 174, page 437.

Note 2 The amount of CIPAC Standard water D used for the test should be in between 400 – 900 mL.

Note 3 The stirring time has to be specified by the manufacturer of the tablet. If the stirring time is not specified by the manufacturer of the tablet, then stir for 10 minutes.

Note 4 A temperature of 60 – 70 °C is recommended. If necessary, the temperature must be adapted to avoid decomposition or volatilisation of formulation components at drying temperature.

Note 5 The gravimetric analysis can be misleading when tablets with insoluble inerts does not completely disintegrate and disperse.