DETERMINATION OF WATER DISPERSIBLE TABLET DISINTEGRATION TIME

Method WHO/M/28
Approved 10 December 1999

1. Outline of method

One entire water dispersible tablet is added to a defined volume of water and mixed by stirring to form a suspension. After standing for a determined period of time the suspension is passed through a 2000 µm sieve. The ease with which the water dispersible tablet is disintegrated in water is determined by the absence of residue left on the sieve.

2. Apparatus

Beaker 1000 mL with a diameter of 102 ± 2 mm (low form)
Stirrer motor with speed control
Stainless steel stirrer propeller type with four fixed stirrer blades set at an angle of 45°. Particular care should be given to the construction of the stirrer with dimensions conforming to those in figure 1.
Sieve 200 mm diameter test sieve of the 2000 µm aperture size.

3. Reagent

WHO Standard hard water. (WHO/M/29)

4. Procedure

Fill the beaker with 1000 mL of WHO standard hard water at 30°C ± 2°C. The stirrer should be centrally located in the beaker and is positioned in such a way that the bottoms of the stirrer blades are 60 mm above the base of the beaker. The pitch of the stirrer blades and the direction of rotation are such that the propeller pushes the water upwards. Add the tablet to the water while not stirring the water. Wait for 1 minute. Switch on the stirrer with the speed set to ± 300 rpm and continue the stirring for 2 min. 30 sec. Then switch off the stirrer and immediately pour the suspension through a 2000 µm sieve. Rinse the beaker out with 50 mL of standard hard water and pour the residue through the 2000 µm sieve.

5. Test result

The absence of residue retained on the 2000 µm sieve indicates that the disintegration of the water dispersible tablet is complete.
Fig. 1.

Side view

\[ \text{\(\bigcirc 6\ mm\)} \]

350 mm

8 mm

50 mm

45°

Shaft

Blade

Plan view

8 mm

50 mm

45°

Blade