



Figure 2.9.4.5. – Cylinder stirring element
 Dimensions in centimetres

Interpretation. The requirements are met if the quantity of active ingredient(s) released from the patch, expressed as the amount per surface area per time unit, is within the prescribed limits at the defined sampling times.

01/2005:20905

2.9.5. UNIFORMITY OF MASS OF SINGLE-DOSE PREPARATIONS

Weigh individually 20 units taken at random or, for single-dose preparations presented in individual containers, the contents of 20 units, and determine the average mass. Not more than 2 of the individual masses deviate from the average mass by more than the percentage deviation shown in Table 2.9.5-1 and none deviates by more than twice that percentage.

For capsules and powders for parenteral use, proceed as described below.

CAPSULES

Weigh an intact capsule. Open the capsule without losing any part of the shell and remove the contents as completely as possible. For soft shell capsules, wash the shell with a suitable solvent and allow to stand until the odour of the solvent is no longer perceptible. Weigh the shell. The mass of the contents is the difference between the weighings. Repeat the procedure with another 19 capsules.

Table 2.9.5-1

| Pharmaceutical Form | Average Mass | Percentage deviation |
|--|--------------------------------------|----------------------|
| Tablets (uncoated and film-coated) | 80 mg or less | 10 |
| | More than 80 mg and less than 250 mg | 7.5 |
| | 250 mg or more | 5 |
| Capsules, granules (uncoated, single-dose) and powders (single-dose) | Less than 300 mg | 10 |
| | 300 mg or more | 7.5 |
| Powders for parenteral use* (single-dose) | More than 40 mg | 10 |
| Suppositories and pessaries | All masses | 5 |
| Powders for eye-drops and powders for eye lotions (single-dose) | Less than 300 mg | 10 |
| | 300 mg or more | 7.5 |

* When the average mass is equal to or below 40 mg, the preparation is not submitted to the test for uniformity of mass but to the test for uniformity of content of single-dose preparations (2.9.6).

POWDERS FOR PARENTERAL USE

Remove any paper labels from a container and wash and dry the outside. Open the container and without delay weigh the container and its contents. Empty the container as completely as possible by gentle tapping, rinse it if necessary with *water R* and then with *alcohol R* and dry at 100-105 °C for 1 h, or, if the nature of the container precludes heating at this temperature, dry at a lower temperature to constant mass. Allow to cool in a desiccator and weigh. The mass of the contents is the difference between the weighings. Repeat the procedure with another 19 containers.