5.2 Uniformity of mass for single-dose preparations

Tablets

Uncoated tablets and film-coated tablets formulated to contain 5% or more of the active ingredient should comply with the following test.

Recommended procedure

Weigh 20 tablets and calculate the average mass. When weighed singly, the deviation of individual masses from the average mass should not exceed the limits given below.

Average mass of tablet	Deviation %	Number of tablets
less than 80 mg	±10.0	minimum 18
	±20.0	maximum 2
80 mg to 250 mg	±7.5	minimum 18
	±15.0	maximum 2
more than 250 mg	±5.0	minimum 18
	±10.0	maximum 2

If film-coated tablets fail this test it may be because of variability in the thickness (mass) of the coatings. In such a case, a test for 5.1 Uniformity of content for single-dose preparations should be applied; if the tablets meet the requirement of this test, they can be considered acceptable.

Capsules

Recommended procedure

Weigh 20 intact capsules individually, and calculate the average mass. The mass of each capsule should be within ±10% of the average mass. If all the capsules do not fall within these limits, weigh the 20 capsules again, taking care to preserve the identity of each capsule, and remove the contents as completely as possible. For soft gelatin capsules, wash the shell with ether or some other suitable solvent and allow it to stand until the odour of the solvent is no longer perceptible. Other means, such as a jet of compressed air, may be used to remove the contents.

Weigh the emptied shells individually and calculate for each capsule the net mass of its contents by subtracting the mass of the shell from the gross mass. Determine the average net content from the sum of the individual net masses. Then determine the difference between each individual net content and the average net content. Deviation of individual net mass from the average net mass should not exceed the limits given below.

Net mass of capsule contents	Deviation %	Number of capsules
less than 300 mg	± 10.0	minimum 18
	± 20.0	maximum 2
300 mg and over	± 7.5	minimum 18
	± 15.0	maximum 2

Oral powders

Weigh 20 units and calculate the average mass. The deviation of individual mass from the average mass should not exceed the limits given above under "Capsules".

Powders for injections

The test applies to powders for injections where the content is more than 40 mg. The recommended procedure is the same as described for capsules. The deviation of individual net mass from the average net mass should not exceed the limits given below.

Deviation %	Number of containers
± 10	minimum 18
± 20	maximum 2

For preparations with a content of less than 40 mg the test for 5.1 Uniformity of content for single-dose preparations applies instead.

Suppositories

Weigh 20 suppositories and calculate the average mass. When the suppositories are weighed singly, the deviation of individual mass from the average mass should not exceed the limits given below.

Deviation %	Number of suppositories
± 5	minimum 18
±10	maximum 2