01/2005:20906

2.9.6. UNIFORMITY OF CONTENT OF SINGLE-DOSE PREPARATIONS

The test for uniformity of content of single-dose preparations is based on the assay of the individual contents of active substance(s) of a number of single-dose units to determine whether the individual contents are within limits set with reference to the average content of the sample.

The test is not required for multivitamin and trace-element preparations and in other justified and authorised circumstances.

Method. Using a suitable analytical method, determine the individual contents of active substance(s) of 10 dosage units taken at random.

Apply the criteria of test A, test B or test C as specified in the monograph for the dosage form in question.

TEST A

Tablets, powders for parenteral use, ophthalmic inserts, suspensions for injection. The preparation complies with the test if each individual content is between 85 per cent and 115 per cent of the average content. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside the limits of 75 per cent to 125 per cent of the average content.

If one individual content is outside the limits of 85 per cent to 115 per cent but within the limits of 75 per cent to 125 per cent, determine the individual contents of another 20 dosage units taken at random. The preparation complies with the test if not more than one of the individual contents of the 30 units is outside 85 per cent to 115 per cent of the average content and none is outside the limits of 75 per cent to 125 per cent of the average content.

TEST B

Capsules, powders other than for parenteral use, granules, suppositories, pessaries. The preparation complies with the test if not more than one individual content is outside the limits of 85 per cent to 115 per cent of the average content and none is outside the limits of 75 per cent to 125 per cent of the average content. The preparation fails to comply with the test if more than 3 individual contents are outside the limits of 85 per cent to 115 per cent of the average content or if one or more individual contents are outside the limits of 75 per cent to 125 per cent of the average content.

If 2 or 3 individual contents are outside the limits of 85 per cent to 115 per cent but within the limits of 75 per cent to 125 per cent, determine the individual contents of another 20 dosage units taken at random. The preparation complies with the test if not more than 3 individual contents of the 30 units are outside the limits of 85 per cent to 115 per cent of the average content and none is outside the limits of 75 per cent to 125 per cent of the average content.

TEST C

Transdermal patches. The preparation complies with the test if the average content of the 10 dosage units is between 90 per cent and 110 per cent of the content stated on the label and if the individual content of each dosage unit is between 75 per cent and 125 per cent of the average content.

01/2005:20907

2.9.7. FRIABILITY OF UNCOATED TABLETS

This test is intended to determine, under defined conditions, the friability of uncoated tablets, the phenomenon whereby tablet surfaces are damaged and/or show evidence of lamination or breakage when subjected to mechanical shock or attrition.

APPARATUS

Use a drum with an internal diameter between 283 and 291 mm and a depth between 36 mm and 40 mm, made of a transparent synthetic polymer with polished internal surfaces and not subject to static build-up (see Figure 2.9.7.-1). One side of the drum is removable. The tablets are tumbled at each turn of the drum by a curved projection with an inside radius between 75.5 mm and 85.5 mm that extends from the middle of the drum to the outer wall. The drum is attached to the horizontal axis of a device that rotates at 25 ± 1 r/min. Thus, at each turn the tablets roll or slide and fall onto the drum wall or onto each other.

METHOD

For tablets weighing up to 0.65 g each, take a sample of twenty tablets; for tablets weighing more than 0.65 g each, take ten tablets. Place the tablets on a sieve no. 1000 and remove any loose dust with the aid of air pressure or a soft brush. Accurately weigh the tablet sample and place the tablets in the drum. Rotate the drum 100 times and remove the tablets. Remove any loose dust from the tablets as before. If no tablets are cracked, split or broken, weigh the tablets to the nearest milligram.

Generally the test is run once. If the results are doubtful or if the mass loss is greater than 1 per cent, repeat the test twice and determine the mean of the 3 tests. A maximum loss of 1 per cent of the mass of the tablets tested is considered to be acceptable for most products.

For tablets having a diameter of 13 mm or greater, problems of reproducibility may be encountered due to frequent irregular tumbling. In such cases, adjust the drum so that the tablets may fall freely and do not bind together when lying next to each other, adjusting the drum so that the axis forms a 10° angle with the base is usually satisfactory.

EXPRESSION OF THE RESULTS

The friability is expressed as the loss of mass and it is calculated as a percentage of the initial mass.

Indicate the number of tablets used.