5.1 Uniformity of content for single-dose preparations

This test applies only where the declared quantity of active ingredient in tablets, capsules, oral powders, single-dose oral suspensions or suppositories is 5 mg or less or is 5% or less of the total formulation or, in the case of sugar-coated and enteric-coated tablets, where the test for 5.2 Uniformity of mass for single-dose preparations does not apply, or for powders for injection or intravenous infusions for which the declared content of active ingredient is 40 mg or less. The test applies to all single-dose suspensions for injection.

For a particular tablet, capsule, oral powder, single-dose oral suspension, suppository or powder for injection or infusion with a strength higher than any indicated in the relevant individual monograph, and for which the declared quantity of active ingredient is outside the above threshold, any requirement for Uniformity of content included in the specific monograph does not apply.

Recommended procedure

Individually determine the amount of active ingredient in each of 10 units using the analytical method specified in the individual monograph under Uniformity of content.

For a particular tablet, capsule oral powder, single-dose oral suspension, suppository or powder for injection or infusion for which the declared quantity of active ingredient is within the threshold stated above, but where no requirement for Uniformity of content is included in the specific monograph, use the analytical procedure described under Assay, suitably modified, where necessary.

Requirements for tablets, single-dose suspensions for injection and single-dose powders for injections or intravenous infusions

Each single unit contains within ±15% of the average amount of the active ingredient. However, if one individual unit deviates by more than ±15% but is within ±25% of the average amount of the active ingredient, examine a further 20 units drawn from the same original sample as the first 10 units. The preparation under test complies only if the amount of active ingredient found in no more than one out of 30 units deviates by more than ±15% of the average amount. None deviates by more than ±25% of the average amount.

Requirements for capsules, single-dose oral powders, single-dose oral suspensions and suppositories

Each single unit contains within ±15% of the average amount of active ingredient. However, if up to three individual units deviate by more than ±15% but are within ±25% of the average amount of the active ingredient, examine a further 20 units drawn from the same original sample as the first 10 units. The preparation under test complies only if the amount of active ingredient found in no more than three out of 30 units deviates by more than ±15% of the average amount. None deviates by more than ±25% of the average amount.