

## 5 2 Uniformity Of Mass For Single Dose Preparations

Practical 7 : Exp 3 : Uniformity Of Weight Of Tablets And ...

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905 UNIFORMITY OF DOSAGE UNITS USP34

Uniformity of mass or weight of tablet dosage form Uniformity of mass or weight of capsule dosage form

content uniformity test

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2.9.40. UNIFORMITY OF DOSAGE UNITS

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General Chapters: <905> UNIFORMITY OF DOSAGE UNITS

(PDF) Demonstration of uniformity of dosage units using ...

5.1 Uniformity of content for single-dose preparations

5.2 Uniformity of mass for single-dose preparations

5 2 Uniformity Of Mass

2.9.5. UNIFORMITY OF MASS OF SINGLE-DOSE PREPARATIONS

Uniformity of content in de Ph. Eur. 1999

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dosage form Uniformity of mass or weight of capsule dosage form

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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. 2.9.5. UNIFORMITY OF MASS OF SINGLE-DOSE . 6. uniformity ... 5.2 Uniformity Of Mass 5.2 Uniformity of mass for single-dose preparations Average mass of tablet Deviation % Number of tablets less than 80 mg  $\pm 10.0$  minimum 18  $\pm 20.0$  maximum 2 80 mg to 250 mg  $\pm 7.5$  minimum 18  $\pm 15.0$  maximum 2 more than 250 mg  $\pm 5.0$  minimum 18  $\pm 10.0$  maximum 2 Net mass of capsule 5.2 Uniformity Of Mass For Single Dose Preparations 5.2 Uniformity Of Mass For Single Dose Preparations 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 25.2 Uniformity Of Mass For Single Dose Preparations 2.9.40.-1). The test for content uniformity of preparations presented in dosage units is based on the assay of the individual contents of active substance(s) of a number of dosage units to determine whether the individual contents are within the limits set. The content uniformity method may be applied in all cases. The test for mass variation ... 2.9.40. UNIFORMITY OF DOSAGE UNIT The uniformity of dosage units can be demonstrated by either of two methods, Content Uniformity or Weight Variation (see Table 1). The test for Content Uniformity is based on the assay of the individual content of drug substance(s) in a number of individual dosage units to determine whether the individual content is within the limits set. The Content Uniformity method may be applied in all cases. General Chapters: <905> UNIFORMITY OF DOSAGE UNIT EUROPEAN PHARMACOPOEIA 5.2 2.9.40. Uniformity of dosage units Figure 2.9.25.-2 - Funnel (dimensions in millimetres) Figure 2.9.25.-3 - Guide (section G-G) (dimensions in millimetres) The gum is artificially chewed by the horizontal pistons, and the vertical piston ensures that the gum stays in the right place between chews. 2.9.40. UNIFORMITY OF DOSAGE UNITS Uniformity or under mass variation, the number of individual dosage units (c<sub>2</sub>) with a content less than  $(1 - L_2 \times 0.01)M$  or more than  $(1 + L_2 \times 0.01)M$  is within the limit defined in Table... (PDF) Demonstration of uniformity of dosage units using ... Uniformity of mass (2.9.5). Single-dose oral powders comply with the test for uniformity of mass of single-dose preparations. If the test for uniformity of content is prescribed for all the active ingredients, the test for uniformity of mass is not required. TOPICAL POWDERS (1997:1166) TESTS Uniformity of content (2.9.6). Unless otherwise prescribed or justified and authorised, single-dose topical powders with a content of active ingredient less than 2 mg or less than 2 per cent of the total ... Uniformity of content in de Ph. Eur. 1999 From the results, we can see that the 7 tablets weighed 664.5 mg, 672.2 mg, 658.3 mg, 676.1 mg, 666.2 mg, 666.7 mg and 661.2 mg respectively are having standard deviation of  $\pm 10.0$ . This is exceeding the limit of only maximum 2 tablets having this type of deviation. Practical 7 : Exp 3 : Uniformity Of Weight Of Tablets And ... From a pharmaceutical quality point of view, the approach taken in the harmonised general chapter on uniformity of dosage units (2.9.40) is considered equivalent to what was previously required in the Ph. Eur. through the general chapters on uniformity of mass of single-dose preparations (2.9.5) and uniformity of content of single-dose ... Quality of medicines questions and answers: Part 1 ... given below. 5.2 Uniformity of mass for single-dose preparations Average mass of tablet Deviation %

Number of tablets less than 80 mg  $\pm 10.0$  minimum 18  $\pm 20.0$  maximum 2 80 mg to 250 mg  $\pm 7.5$  minimum 18  $\pm 15.0$  maximum 2 more than 250 mg  $\pm 5.0$  minimum 18 5.2 Uniformity of mass for single-dose preparations 5 2 uniformity of mass for single dose 5 2 Uniformity Of Mass For Single Dose Preparations | www ...also included standards for content uniformity, weight variation, and loss of mass—while the ... 5 Na Zhao et al., 30 November 2010, 401(1-2), ...Guidance for Industry uniformity of dosage units by Mass Variation instead of the Content Uniformity test if the concentration relative standard deviation (RSD) of the drug substance in the final dosage units is not more than 2%, based on process validation data and development data, and if there has been regulatory ap-905 UNIFORMITY OF DOSAGE UNITS USP34 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 certain powders for injections when specified in individual monographs.

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The uniformity of dosage units can be demonstrated by either of two methods, Content Uniformity or Weight Variation (see Table 1). The test for Content Uniformity is based on the assay of the individual content of drug substance(s) in a number of individual dosage units to determine whether the individual content is within the limits set. The Content Uniformity method may be applied in all cases.

*Uniformity of mass or weight of tablet dosage form* *Uniformity of mass or weight of capsule dosage form*

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*content uniformity test*

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*Content Uniformity of Tablet Ph. Eur. Weight Uniformity Test* **Basic Geotechnical Engineering [15cv45]** [How to perform Uniformity of Dosage | #Qualitycontrol #Pharmajobs | #Chromatography | #Hindi](#) *Evaluation of tab (wt. variation / content uniformity) tests*

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5 2 Uniformity Of Mass For Single Dose Preparations 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

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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.

2.9.5. UNIFORMITY OF MASS OF SINGLE-DOSE . 6. uniformity ...

uniformity of dosage units by Mass Variation instead of the Content Uniformity test if the concentration relative standard deviation (RSD) of the drug substance in the final dosage units is not more than 2%, based on process validation data and development data, and if there has been regulatory ap-

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#### 2.9.40. UNIFORMITY OF DOSAGE UNITS

EUROPEAN PHARMACOPOEIA 5.2 2.9.40. Uniformity of dosage units Figure 2.9.25.-2 -Funnel (dimensions in millimetres) Figure 2.9.25.-3 - Guide (section G-G) (dimensions in millimetres) The gum is artificially chewed by the horizontal pistons, and the vertical piston ensures that the gum stays in the right place between chews.

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From the results, we can see that the 7 tablets weighed 664.5 mg, 672.2 mg, 658.3 mg, 676.1 mg, 666.2 mg, 666.7 mg and 661.2 mg respectively are having standard deviation of  $\pm 10.0$ . This is exceeding the limit of only maximum 2 tablets having this type of deviation.

#### General Chapters: <905> UNIFORMITY OF DOSAGE UNITS

#### (PDF) Demonstration of uniformity of dosage units using ...

Uniformity of mass or weight of tablet dosage form Uniformity of mass or weight of capsule dosage form

content uniformity test

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#### Classification

#### 5.1 Uniformity of content for single-dose preparations

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#### 5.2 Uniformity Of Mass

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#### 2.9.5. UNIFORMITY OF MASS OF SINGLE-DOSE PREPARATIONS

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