

5 2 Uniformity Of Mass For Single Dose Preparations

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5 2 Uniformity Of Mass

5.2 Uniformity of mass for single-dose preparations

The deviation of individual net mass from the average net mass should not exceed the limits given below

52 Uniformity of mass for single-dose preparations	Average mass of tablet	Deviation %	Number of tablets
less than 80 mg	± 100	minimum 18	± 200
maximum 2 80 mg to 250 mg	± 75	minimum 18	± 150
more than 250 mg	± 50	minimum 18	

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

295 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

Final text for revision of The International Pharmacopoeia

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 52 Uniformity of mass for single-dose preparations does not apply, or for certain powders for injections when specified in individual monographs

2.9.40. UNIFORMITY OF DOSAGE UNITS

2940 Uniformity of dosage units EUROPEAN PHARMACOPOEIA 70 Table 2940-1 - Application of Content Uniformity (CU) and Mass Variation (MV) test for dosage forms

Dosage forms	Type	Sub-Type	Dose and ratio of active substance
≥ 25 mg and ≥ 25 per cent			< 25 mg or < 25 per cent

5.1 Uniformity of content for single-dose preparations

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 52 Uniformity of mass for single-dose preparations does not apply, or for powders for injection

Uniformity of Dosage Units, Part 1: Acceptance Value

label claim (LC) (where M may be x, 985 or 1015% LC) or more than 1015% LC (where M may be x, 985 or T% LC) See United States Pharmacopeia (USP) (1) for more detail The concept of acceptance value must be redefined to remove bias and more closely reflect quality targets This paper describes how this can be done Uniformity of Dosage Units,

European Medicines Agency

215 If a correction factor is called for when different procedures are used for assay of the preparation and for the Content Uniformity Test, the correction factor should be specified and justified in the application dossier

INTERNATIONAL PHARMACOPOEIA MONOGRAPH ON ORAL ...

Uniformity of content See the general requirements 51 Uniformity of content of single-dose preparations Single-dose oral powders with a content of active ingredient of less than 5 mg or less than 5 per cent of the total mass comply with the test , unless otherwise specified in the individual monograph

11/21/2016 30(4) Harmonization: <905> UNIFORMITY OF ...

11/21/2016 30(4) Harmonization: <905> UNIFORMITY OF DOSAGE UNITS adopts the global text in the European Pharmacopoeia, Supplement 52, official December 2004 and the JP adopts the global text in the JP XV, official April 2006 Content Uniformity requirements; 2

905 UNIFORMITY OF DOSAGE UNITS USP34

2 [905] Uniformity of Dosage Units Official December 1, 2011 in conditions of normal use, and express the results as de-in which the terms are as defined in Table 2 livered dose Calculate the acceptance value (see Table 2) Calculation of Acceptance Value—Calculate the accep-tance value by the formula: Table 2

Uniformity of Dosage Units (BP 2011 & USP 34)

Uniformity of Dosage Units (BP 2011, USP 34) Frequently asked questions Q: If uncoated tablet contains 2 drug substances but only one of them meets the requirement for WV, how can the requirement be met? A: In the case of a two-component tablet, uniformity ...

Weight and content uniformity of lorazepam half-tablets: A ...

the content of spilt-halves of lorazepam 25 mg tablets Weight variation and drug content of lor-azepam half-tablets were evaluated according to the European Pharmacopoeia tests Only one indi-vidual mass of the 30 half tablets was outside the limits of 85–115% of the average mass, but since it

Guidelines and Best Practices for Uniformity in Mass Appraisal

Guidelines and Best Practices for Uniformity in Mass Appraisal October 2019 5 The Federal Railroad Revitalization (4-R) Act is found in 49 USCS § 11501 and prohibits discrimination against railroad property Another Federal Act, the TEFRA Act (Tax Equity and Fiscal Responsibility Act of 1982),

Standard on Mass Appraisal of Real Property

Mass appraisal requires complete and accurate data, effective valuation models, and proper management of resources Section 2 introduces mass appraisal Section 3 focuses on the collection and maintenance of property data Section 4 summarizes the primary considerations in valuation methods, including the role of the three approaches to value in

FROM UNIFORMITY

mass importers EPT 02 FROM UNIFORMITY TO DIVERSITY 5 focused around a handful of industrially-pro-duced varieties of rice, maize, wheat and other staple crops Eroding the genetic pool exacerbates risks in food systems by limiting the options available to future generations for

CRD-C55-92 Test Method for Within-Batch Uniformity of ...

the uniformity of distribution of constituents within a 52 The very first and very last concrete to be dis-charged should not be sampled; specifically, the three microwave oven until constant mass is achieved 92 The compressive strength of each specimen

Content Uniformity (CU) testing for the 21st Century: CDER ...

Meeting USP <905> content uniformity with < 5% potency loss may provide reasonable assurance that strengths do not lose order of potency on stability 12 Loss of mass (crumbs) typically 1-2%

Cylinder stirring element

Suppositories and pessaries All masses 5 Powders for eye-drops and powders for eye lotions (single-dose) Less than 300 mg 300 mg or more 10 75 *
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 (296)

The Morphology and Uniformity of Circumstellar OH/H 2 O ...

and observed them at different scales to reveal the uniformity of mass loss through different layers close to the star This includes observing nearby masers that trace the molecular shell structure