BRIEFING

〈**905**〉 **Uniformity of Dosage Units,** *USP* 32 page 382 and page 1290 of *PF* 34(5) [Sept.–Oct. 2008]. This general test chapter is revised to reduce the quantity of national, USP-specific text and more completely represent the harmonized text agreed upon by the Pharmacopeial Discussion Group. The texts of this chapter as presented in the *European Pharmacopoeia*, the *Japanese Pharmacopoeia*, and the *USP* are undergoing evaluation by ICH for Regulatory Approval of Analytical Procedures and Acceptance Criteria. Communications received from the European Pharmacopoeia Commission Secretariat recommended the reduction in *USP*-specific national text to assist the ICH evaluation and approval. USP determined that the changes would not only enhance conformance with the harmonized text but reduce redundant verbiage.

Changes to the *USP* text include the following:

1. Reduction in the number of references to the specific monograph and instead merely citing the specification. In the *USP*, the specification is found in the monograph and thus additional wording to that effect is seen as redundant.
2. Elimination of the evaluation of a special procedure and replacement with harmonized text that refers in more general terms to the possible need to apply a correction factor where differences are observed between the results of the assay and the special procedure for content uniformity.
3. Simplification of the list of dosage forms presented in *Table 1*. This change is also made to the procedures and *Criteria* sections for *Content Uniformity* and *Weight Variation* test sections. The national text procedures and criteria for suppositories, transdermal systems, inhalations packaged in premetered dosage units, and solutions for inhalation packaged in glass or plastic ampuls and intended for use in nebulizers are thereby revised.

(PDF: W. Brown.)
RTS—C71696

〈905〉 UNIFORMITY OF DOSAGE UNITS

Change to read:

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This general chapter is harmonized with the corresponding texts of the *European Pharmacopoeia* and the *Japanese Pharmacopoeia*. Portions of the general chapter text that are national *USP* text, and are not part of the harmonized text, are marked with symbols (✦ ✦) to specify this fact.

■2S (*USP32*)

✦ [NOTE— In this chapter, *unit* and *dosage unit* are synonymous.] ✦

To ensure the consistency of dosage units, each unit in a batch should have a drug substance content within a narrow range around the label claim. Dosage units are defined as dosage forms containing a single dose or a part of a dose of drug substance in each unit. The uniformity of dosage units specification is not intended to apply to suspensions, emulsions, or gels in unit-dose containers intended for ✦ ~~topical.~~ ✦

▲ external, cutaneous ▲ *USP33*

administration.

The term "uniformity of dosage unit" is defined as the degree of uniformity in the amount of the drug substance among dosage units. Therefore, the requirements of this chapter apply to each drug substance being comprised in dosage units containing one or more drug substances, unless otherwise specified ✦ ~~in the individual monograph.~~ ✦

▲ elsewhere in this pharmacopeia. ▲ *USP33*

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*

▲ of preparations presented in dosage units ▲ *USP33*

is based on the assay of the individual content of drug substance(s) in a number of ✦ ~~individual.~~ ✦

▲ ▲ *USP33*

dosage units to determine whether the individual content is within the limits set. The *Content Uniformity* method may be applied in all cases. ✦ ~~The test for *Content Uniformity* is required for those dosage forms described in *(C1)–(C6)* below:~~

~~(C1)~~	~~coated tablets, other than film-coated tablets containing 25 mg or more of a drug substance that comprises 25% or more (by weight) of one tablet;~~
~~(C2)~~	~~transdermal systems;~~
~~(C3)~~	~~suspensions or emulsions or gels in single-unit containers or in soft capsules that are intended for systemic administration only (not for those drug products that are intended for topical administration);~~
~~(C4)~~	~~inhalations (other than solutions for inhalation packaged in glass or plastic ampuls and intended for use in nebulizers) packaged in premetered dosage units. For inhalers and premetered dosage units labeled for use with a named inhalation device, also see *Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers* 〈601〉 ;~~
~~(C5)~~	~~solids (including sterile solids) that are packaged in single-unit containers and that contain active or inactive added substances, except that the test for *Weight Variation* may be applied in the special cases stated in *(W3)* below; and~~
~~(C6)~~	~~suppositories.~~ ✦

▲ ▲ *USP33*

The test for ✦ *Weight* ✦ *Variation* is applicable for the following dosage forms:

(W1)	✦ ~~solutions for inhalation that are packaged in glass or plastic ampuls and intended for use in nebulizers, and oral~~ ✦ Solutions ✦ ~~packaged~~ ✦ ▲ enclosed ▲ *USP33* in unit-dose containers and into soft capsules;
(W2)	solids (including ▲ powders, granules, and ▲ *USP33* sterile solids) that are packaged in single-unit containers and contain no ~~added substances, whether active or inactive~~ ▲ active or inactive added substances; ▲ *USP33*
(W3)	solids (including sterile solids) that are packaged in single-unit containers, with or without ~~added substances, whether active or inactive,~~ ▲ active or inactive added substances, ▲ *USP33* that have been prepared from true solutions and freeze-dried in the final containers and are labeled to indicate this method of preparation; and
(W4)	hard capsules, uncoated tablets, or film-coated tablets, containing 25 mg or more of a drug substance comprising 25% or more, by weight, of the dosage unit or, in the case of hard capsules, the capsule contents, except that uniformity of other drug substances present in lesser proportions is demonstrated by meeting *Content Uniformity* requirements.

The test for *Content Uniformity* is required for all dosage forms not meeting the above conditions for the ✦ *Weight* ✦ *Variation* test. ✦ Where compliance with the *Content Uniformity* test is required, then, by application of the provision for use of alternative methods provided in the *General Notices* section of this *Pharmacopeia*, it is possible for manufacturers to ensure this compliance by application of the *Weight Variation* test where the concentration relative standard deviation (RSD) of the drug substance in the final dosage units is not more than 2%. This RSD determination may be based on the manufacturer's process validation and product development data. ✦ The concentration RSD is the RSD of the concentration per dosage unit (w/w or w/v), where concentration per dosage unit equals the assay result per dosage unit divided by the

individual dosage unit weight. See the RSD formula in *Table 2*. ✦ Where the *Weight Variation* test is used in this way, the product must, if tested, nevertheless comply with the official compendial test for *Content Uniformity.* ✦

Table 1. Application of Content Uniformity (CU) and Weight Variation (WV) Tests for Dosage Forms

Dosage Form	Type	Subtype	Dose & Ratio of Drug Substance	
			≥25 mg &≥25%	<25 mg or<25%
Tablets	Uncoated		WV	CU
	Coated	Film	WV	CU
		Others	CU	CU
Capsules	Hard		WV	CU
	Soft	Suspension, emulsion, or gel	CU	CU
		Solutions	WV	WV
Solids in single-unit containers	Single component		WV	WV
	Multiple components	Solution freeze-dried in final container	WV	WV
		Others	CU	CU
✦ ~~Suspension, emulsion, or gel for systemic use only, packaged in single-unit containers~~ ✦			✦ ~~CU~~ ✦	✦ ~~CU~~ ✦ ▲ USP33
Solutions ✦ ~~for inhalation packaged in glass or plastic ampuls and intended for use in nebulizers, and oral~~ ✦ ~~solutions~~ ✦ ~~packaged~~ ✦ in unit-dose containers ✦ and into soft capsules ✦			WV	WV
✦ ~~Inhalations (other than solutions for inhalation packaged in glass or plastic ampuls and intended for use in nebulizers) packaged in premetered dosage units~~ ✦			✦ ~~CU~~ ✦	✦ ~~CU~~ ✦
✦ ~~Transdermal systems~~ ✦			✦ ~~CU~~ ✦	✦ ~~CU~~ ✦
✦ ~~Suppositories~~ ✦			✦ ~~CU~~ ✦	✦ ~~CU~~ ✦ ▲ USP33
Others			CU	CU

Change to read:

CONTENT UNIFORMITY

Select not fewer than 30 units, and proceed as follows for the dosage form designated. ✦ ~~Where the amount of drug substance in a single dosage unit differs from that required in the *Assay*, adjust the degree of dilution of the solutions and/or the volume of aliquots so that the concentration of the drug substances in the final solution is of the same order as that obtained in the *Assay* procedure; or, in the case of a titrimetric assay, use a titrant of a different concentration, if necessary, so that an adequate volume of titrant is required (see *Titrimetry* ⟨541⟩); see also *Procedures* under *Tests and Assays* in the *General Notices and Requirements*. If any such modifications are made in the *Assay* procedure set forth in the individual monograph, make the appropriate corresponding changes in the calculation formula and titration factor.~~

~~Where a special *Procedure for content uniformity* is specified in the test for *Uniformity of dosage units* in the individual monograph, make any necessary correction of the results obtained as follows.~~

1. ~~Prepare a composite specimen of a sufficient number of dosage units to provide the amount of specimen called for in the *Assay* in the individual monograph plus the amount required for the special *Procedure for content uniformity* in the monograph by finely powdering tablets or mixing the contents of capsules or oral solutions, suspensions, emulsions, gels, or solids in single-unit containers to obtain a homogeneous mixture. If a homogeneous mixture cannot be obtained in this manner, use suitable solvents or other procedures to prepare a solution containing all of the drug substance, and use appropriate aliquot portions of this solution for the specified procedures.~~
2. ~~Assay separate, accurately measured portions of the composite specimen of capsules or tablets or suspensions or inhalations or solids in single-unit containers, both (a) as directed in the *Assay*, and (b) using the special *Procedure for content uniformity* in the monograph.~~
3. ~~Calculate the weight of drug substance equivalent to 1 average dosage unit, by (a) using the results obtained by the *Assay* procedure, and by (b) using the results obtained by the special procedure.~~
4. ~~Calculate the correction factor, *F*, by the formula:~~

   $$\cancel{F = W/P}$$

   ~~in which *W* is the weight of drug substance equivalent to 1 average dosage unit obtained by the *Assay* procedure, and *P* is the weight of drug substance equivalent to 1 average dosage unit obtained by the special procedure. If~~

   $$\cancel{\frac{100|W - P|}{W}}$$

   ~~is greater than 10, the use of a correction factor is not valid.~~
5. ~~The correction factor is to be applied only if *F* is not less than 1.030 nor greater than 1.100, or not less than 0.900 nor greater than 0.970. If *F* is between 0.970 and 1.030, no correction is required.~~
6. ~~If *F* lies between 1.030 and 1.100, or between 0.900 and 0.970, calculate the weight of drug substance in each dosage unit by multiplying each of the weights found using the special procedure by *F*.~~ ♦

▲ Where different procedures are used for assay of the preparation and for the content uniformity test, it may be necessary to establish a correction factor to be applied to the results of the latter. ▲ *USP33*

♦ ~~**Uncoated, Coated, or Molded Tablets, Capsules, Oral Solutions in Unit-Dose Containers, Suspensions or Emulsions or Gels in Single-Unit Containers (that are intended for systemic administration only), and Solids (including Sterile Solids) in Single-Unit Containers**~~ ♦

▲ **Solid Dosage Forms** ▲ *USP33*

— Assay 10 units individually ♦ ~~as directed in the *Assay* in the individual monograph, unless otherwise specified in the *Procedure for content uniformity* in the individual monograph.~~ ♦

▲ using an appropriate analytical method. ▲ *USP33*

Calculate the acceptance value ~~as directed below~~

▲ ▲ *USP33*

■ (see *Table 2*). ■2S (*USP32*)

◆ ~~For oral solutions in unit-dose containers, and for suspensions, emulsions, or gels in single-unit containers that are intended for systemic administration only,~~ ◆

▲ **Liquid Dosage Forms—** ▲ *USP33*

Carry out the *Assay* on the amount of well-mixed material that ~~drains from an individual container in not more than 5 seconds,~~

■ is removed from an individual container in conditions of normal use, and express the results as delivered dose. ■2S (*USP32*)

◆ ~~or for highly viscous products, conduct the *Assay* on the amount of well-mixed material that is obtained by quantitatively removing the contents from an individual container~~ ◆ ~~, and express the results as the delivered dose.~~

▲ ▲ *USP33*

■ Calculate the acceptance value (see *Table 2*). ■2S (*USP32*)

CALCULATION OF ACCEPTANCE VALUE— Calculate the acceptance value by the formula:

$$\left| M - \overline{X} \right| + ks$$

in which the terms are as defined in *Table 2*.

Table 2

Variable	Definition	Conditions	Value
$\overline{X}$	Mean of individual contents (χ_1, χ_2, … , χ_n), expressed as a percentage of the label claim		
χ_1, χ_2, … , χ_n	Individual contents of the units tested, expressed as a percentage of the label claim		
n	Sample size (number of units in a sample)		
k	Acceptability constant	If n = 10, then k =	2.4
		If n = 30, then k =	2.0

Variable	Definition	Conditions	Value
s	Sample standard deviation		$\left[\frac{\sum_{i=1}^{n}\left(\chi_i - \overline{X}\right)^2}{n-1}\right]^{\frac{1}{2}}$
RSD	Relative standard deviation (the sample standard deviation expressed as a percentage of the mean)		$\frac{100s}{\overline{X}}$

Variable	Definition	Conditions	Value
M (case 1) to be applied when *T* ≤101.5	Reference value	If 98.5% ≤ $\overline{X}$ ≤101.5%, then	
		If $\overline{X}$ <98.5%, then	*M* = 98.5% (*AV* = 98.5 – $\overline{X}$ + *ks*)
		If $\overline{X}$ >101.5%, then	*M* = 101.5% (*AV* = $\overline{X}$ – 101.5 + *ks*)
M (case 2) to be applied when *T* >101.5	Reference value	If 98.5 ≤ $\overline{X}$ ≤ *T,* then	*M* = $\overline{X}$ (*AV* = *ks*)
		If $\overline{X}$ <98.5%, then	*M* = 98.5% (*AV* = 98.5 – $\overline{X}$ + *ks)*
		If $\overline{X}$ >*T,* then	*M* = *T*% (*AV* = $\overline{X}$ – *T* + *ks)*
Acceptance value *(AV)*			general formula: $\left\lvert M - \overline{X} \right\rvert + ks$ (Calculations are specified above for the different cases.)
L1	Maximum allowed acceptance value		*L1* = 15.0 unless otherwise specified ✦ ~~in the individual monograph~~ ✦ ▲ ▲ *USP33*
L2	Maximum allowed range for deviation of each dosage unit tested from the calculated value of *M*	On the low side, no dosage unit result can be less than [1 – (0.01)(*L2*)]*M,* while on the high side no dosage unit result can be greater than [1 + (0.01)(*L2*)]*M.* (This is based on an *L2* value of 25.0.)	*L2* = 25.0 unless otherwise specified ✦ ~~in the individual monograph~~ ✦ ▲ ▲ *USP33*

Variable	Definition	Conditions	Value
T	Target content per dosage unit at the time of manufacture, expressed as a percentage of the label claim. For purposes of this Pharmacopeia, unless otherwise ~~specified in the individual monograph, *T* is the average of the limits specified in the potency definition in the individual monograph.~~ ■ stated in the individual monograph, *T* is 100.0%, and for manufacturing purposes, *T* is the manufacturer's approved target test amount value at the time of manufacture. ■ 2S (*USP32*)		

~~✦ **Suppositories, Transdermal Systems, and Inhalations Packaged in Premetered Dosage Units—** [NOTE— Acceptance value calculations are not required for these dosage forms.] Assay 10 units individually as directed in the *Assay* in the individual monograph, unless otherwise specified in the *Procedure for content uniformity*. ✦~~

▲ ▲ *USP33*

Change to read:

✦ WEIGHT ✦ VARIATION

~~Select not fewer than 30 dosage units, and proceed as follows for the dosage form designated. The result of the *Assay,* ✦ obtained as directed in the individual monograph, ✦ is designated as result *A,* expressed as % of label claim (see *Calculation of Acceptance Value*). Assume that the concentration (weight of drug substance per weight of dosage unit) is uniform. [NOTE— Specimens other than these test units may be drawn from the same batch for assay determinations. ✦]~~

▲ Carry out an assay for the drug substance(s) on a representative sample of the batch using an appropriate analytical method. This value is result A, expressed as percent of label claim (see *Calculation of Acceptance Value*). Assume that the concentration (weight of drug substance per weight of dosage unit) is uniform. Select not fewer than 30 dosage units, and proceed as follows for the dosage form designated. ▲ *USP33*

Uncoated or Film-Coated Tablets— Accurately weigh 10 tablets individually. Calculate the ✦ ~~drug substance~~ ✦

▲ ▲ *USP33*

content, expressed as % of label claim, of each tablet from the ✦ weight ✦ of the individual tablet and the result of the *Assay*. Calculate the acceptance value.

Hard Capsules— Accurately weigh 10 capsules individually, taking care to preserve the identity of each capsule. Remove the contents of each capsule by a suitable means. Accurately weigh the emptied shells individually, and calculate for each capsule the net ✦ weight ✦ of its contents by subtracting the ✦ weight ✦ of the shell from the respective gross ✦ weight ✦ . Calculate the drug substance content ✦ ~~expressed as % of label claim,~~ ✦

▲ ▲ *USP33*

of each capsule from the ✦ net weight ✦ of the individual capsule ✦ content ✦ and the result of the assay. Calculate the acceptance value.

Soft Capsules— Accurately weigh 10 intact capsules individually to obtain their gross ✦ weights ✦ , taking care to preserve the identity of each capsule. Then cut open the capsules by means of a suitable clean, dry cutting instrument such as scissors or a sharp open blade, and remove the contents by washing with a suitable solvent. Allow the occluded solvent to evaporate from the shells at room temperature over a period of about 30 minutes, taking precautions to avoid uptake or loss of moisture. Weigh the individual shells, and calculate the net contents. Calculate the drug substance content ✦ ~~expressed as % of label claim,~~ ✦

▲ ▲ *USP33*

in each capsule from the ✦ ~~net~~

▲ ▲ *USP33*

weight ✦ of product removed from the individual capsules and the result of the assay. Calculate the acceptance value.

~~**Solids**~~ ✦ ~~**(Including Sterile Solids) in Single-Unit Containers**~~ ✦

▲ **Solid Dosage Forms Other Than Tablets and Capsules** ▲ *USP32*

— Proceed as directed for *Hard Capsules,* treating each unit as described therein. Calculate the acceptance value.

✦ ~~**Oral Solutions Packaged in Unit-Dose Containers**~~ ✦

▲ **Liquid Dosage Forms** ▲ *USP33*

— Accurately weigh the amount of liquid that ~~drains in not more than 5 seconds~~

■ is removed ■ 2S (*USP32*)

from each of 10 individual containers

■ in conditions of normal use. ■ 2S (*USP32*)

If necessary, compute the equivalent volume after determining the density. Calculate the drug substance content ✦ ~~expressed as % of label claim, in the liquid drained from each unit from the net weight of the individual container content~~ ✦

▲ in each container from the mass of product removed from the individual containers ▲ *USP33*

and the result of the assay. Calculate the acceptance value.

Calculation of Acceptance Value— Calculate the acceptance value as shown in *Content Uniformity,* except that the individual contents of the units are replaced with the individual estimated contents defined below.

$\chi_1, \chi_2, \ldots, \chi_n$	=	individual estimated contents of the units tested, where $\chi_i = w_i \times A / \overline{W}$
$w_1, w_2, \ldots, w_n$	=	individual ✦ weights ✦ of the units tested ~~for weight variation,~~ ■ ■2S (*USP32*)
A	=	content of drug substance (% of label claim) ✦ ~~determined as described in the *Assay*, and~~ ✦ ▲ obtained using an appropriate analytical method ▲ *USP33*
$\overline{W}$	=	mean of individual ✦ weights ✦ ($w_1, w_2, \ldots, w_n$) ~~of the units used in the Assay.~~ ■ ■2S (*USP32*)

✦ ~~**Solutions for Inhalation Packaged in Glass or Plastic Ampuls and Intended for Use in Nebulizers—** [NOTE— Acceptance value calculations are not required for these dosage forms.] Accurately weigh 10 containers individually, taking care to preserve the identity of each container. Remove the contents of each container by a suitable means. Accurately weigh the emptied containers individually, and calculate for each container the net weight of its contents by subtracting the weight of the container from the respective gross weight. From the results of the *Assay*, obtained as directed in the individual monograph, calculate the drug substance content, expressed as % of label claim, in each of the containers.~~ ✦

▲ ▲ *USP33*

Change to read:

CRITERIA

Apply the following criteria, unless otherwise specified. ✦ ~~in the individual monograph~~ ✦

▲ ▲ *USP33*

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✦ ~~**Uncoated, Coated, or Molded Tablets, Capsules, Oral Solutions in Unit-Dose Containers, Suspensions or Emulsions or Gels in Single-Unit Containers (that are intended for systemic administration only), and Solids (including Sterile Solids) in Single-Unit Containers**~~ ✦

▲ **Solid and Liquid Dosage Forms** ▲ *USP33*

— The requirements for dosage uniformity are met if the acceptance value of the first 10 dosage units is less than or equal to *L1*%. If the acceptance value is greater than *L1*%, test the next 20 units, and calculate the acceptance value. The requirements are met if the final acceptance value of the 30 dosage units is less than or equal to *L1*%, and no individual content of ✦ any ✦ dosage unit is less than [1 − (0.01)(*L2*)] *M* nor more than [1 + (0.01)(*L2*)] *M* ✦ as specified ✦ in the *Calculation of Acceptance Value* under *Content Uniformity* or under ✦ *Weight* ✦ *Variation.* Unless otherwise specified, ✦ ~~in the individual monograph,~~ ✦

▲ ▲ *USP33*

L1 is 15.0 and *L2* is 25.0.

✦ ~~**Suppositories—**~~

~~*Limit A* (if the average of the limits specified in the potency definition in the individual monograph is 100.0 percent or less) —Unless otherwise specified in the individual monograph, the requirements for dosage uniformity are met if the amount of the drug substance in each of the 10 dosage units as determined from the *Content Uniformity* method lies within the range of 85.0% to 115.0% of the label claim, and the RSD is less than or equal to 6.0%.~~

~~If 1 unit is outside the range of 85.0% to 115.0% of label claim, and no unit is outside the range of 75.0% to 125.0% of label claim, or if the RSD is greater than 6.0%, or if both conditions prevail, test 20 additional units. The requirements are met if not more than 1 unit of the 30 is outside the range of 85.0% to 115.0% of label claim, and no unit is outside the range of 75.0% to 125.0% of label claim and the RSD of the 30 dosage units does not exceed 7.8%.~~

~~*Limit B* (if the average of the limits specified in the potency definition in the individual monograph is greater than 100.0 percent)—~~

1. ~~If the average value of the dosage units tested is 100.0 percent or less, the requirements are as in *Limit A*.~~
2. ~~If the average value of the dosage units tested is greater than or equal to the average of the limits specified in the potency definition in the individual monograph, the requirements are as specified under *Limit A*, except that the words "label claim" are replaced by the words "label claim multiplied by the average of the limits specified in the potency definition in the monograph divided by 100".~~
3. ~~If the average value of the dosage units tested is between 100 percent and the average of the limits specified in the potency definition in the individual monograph, the requirements are as specified under *Limit A*, except that the words "label claim" are replaced by the words "label claim multiplied by the average value of the dosage units tested (expressed as a percent of label claim) divided by 100".~~ ◆

◆ ~~**Transdermal Systems, and**~~

■ ~~■ *2S (USP32)*~~

~~**Inhalations Packaged in Premetered Dosage Units,**~~

■ ~~**and Solutions for Inhalation Packaged in Glass or Plastic Ampuls and Intended for Use in Nebulizers**~~ ■ ~~*2S (USP32)*~~

~~*Limit A* (if the average of the limits specified in the potency definition in the individual monograph is 100.0 percent or less) —Unless otherwise specified in the individual monograph, the requirements for dosage uniformity are met if the amount of the drug substance in not fewer than 9 of the 10 dosage units as determined from the *Content Uniformity* method (or, in the case of solutions for inhalation packaged in glass or plastic ampuls and intended for use in nebulizers, from either the *Table 1* or the *Weight Variation* method) lies within the range of 85.0% to 115.0% of label claim, and no unit is outside the range of 75.0% to 125.0% of label claim, and the RSD of the 10 dosage units is less than or equal to 6.0%.~~

~~If 2 or 3 dosage units are outside the range of 85.0% to 115.0% of label claim, but not outside the range of 75.0% to 125.0% of label claim, or if the RSD is greater than 6.0% or if both conditions prevail, test 20 additional units. The requirements are met if not more than 3 units of the 30 are outside the range of 85.0% to 115.0% of label claim and no unit is outside the range of 75.0% to 125.0% of label claim, and the RSD of the 30 dosage units does not exceed 7.8%.~~

~~*Limit B* (if the average of the limits specified in the potency definition in the individual monograph is greater than 100.0 percent)—~~

1. ~~If the average value of the dosage units tested is 100.0 percent or less, the requirements are as in *Limit A*.~~
2. ~~If the average value of the dosage units tested is greater than or equal to the average of the limits specified in the potency definition in the individual monograph, the requirements are as specified under *Limit A,* except that the words "label claim" are replaced by the words "label claim multiplied by the average of the limits specified in the potency definition in the monograph divided by 100".~~
3. ~~If the average value of the dosage units tested is between 100 percent and the average of the limits specified in the potency definition in the individual monograph, the requirements are as specified under *Limit A,* except that the words "label claim" are replaced by the words "label claim multiplied by the average value of the dosage units tested (expressed as a percent of label claim) divided by 100".~~ ◆

▲ ▲ *USP33*

Auxiliary Information— Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee

General Chapter	William E. Brown Senior Scientist 1-301-816-8380	(PDF05) Pharmaceutical Dosage Forms 05

USP32–NF27 Page 382
USP32–NF27 Supplement : No. 2 Page 4156
Interim Revision Announcement: *USP29–NF24* No. 6 Page 1653
Pharmacopeial Forum: Volume No. 35(3) Page 724