GENERAL INFORMATION

International Harmonization Implemented in the Japanese Pharmacopoeia Sixteenth Edition

Add the following:

November 2012 (Corr.1)

Harmonized items	JP16 (Partial revision)	Remarks
Gelatin (Gelling Grade)	**Gelatin**	
Definition	Definition	In JP, "Purified protein obtained from collagen of animals by enzymatic hydrolysis" is not included.
Identification A	Identification (1)	
Identification B	Identification (2)	
pH	pH	
Conductivity	Conductivity	
Sulphur dioxide	Purity (7) Sulfur dioxide	
Peroxides	Purity (6) Peroxides	
Gel strength (Bloom value)	Gel strength (Bloom value)	
Iron	Purity(2) Iron	
Chromium	Purity (3) Chromium	
Zinc	Purity (4) Zinc	
Loss on drying	Loss on drying	
Microbial contamination	Microbial limit	
Storage	Containers and storage	
Labelling	Definition	

Change the following:

November 2010 (Rev.1)

Harmonized items	JP16 (Partial revision)	Remarks
Uniformity of Dosage Units	**6.02 Uniformity of Dosage Units**	
(Introduction)	(Introduction)	JP's particular description: Additional explanation on Liquids. Additional explanation for the part not containing drug substance.
Content uniformity	1. Content Uniformity	
Solid dosage forms	(i) Solid dosage forms	
Liquid or Semi-Solid dosage forms	(ii) Liquid or Semi-Solid dosage forms	
Calculation of acceptance value	1.1. Calculation of Acceptance Value	
Mass variation	2. Mass Variation	JP's particular description: Assuming that the concentration of drug substance is uniform in each lot.
Uncoated or film-coated tablets	(i) Uncoated or film-coated Tablets	
Hard capsules	(ii) Hard Capsules	
Soft capsules	(iii) Soft Capsules	
Solid dosage forms other than tablets and capsules	(iv) Solid dosage forms other than tablets and capsules	
Liquid dosage forms	(v) Liquid dosage forms	The phrase “in conditions of normal use. If necessary, compute the equivalent volume after determining the density.” is deleted.
Calculation of acceptance value	2.1. Calculation of Acceptance Value	
Criteria	3. Criteria	
Solid, Semi-Solid and Liquid dosage forms	(i) Solid, Semi-Solid and Liquid dosage forms	
Table 1 Application of content uniformity (CU) and mass variation (MV) test for dosage forms	Table 6.02-1 Application of Content Uniformity (CU) and Mass Variation (MV) Test for Dosage Forms	JP’s particular description: Addition of “(divided forms, lyophilized forms)” and “(true solution)”.
Table 2	Table 6.02-2	