

PDG State of Work

As of July, 2020

Harmonization Item	Coordinating Pharmacopoeia	Stage
General Methods relevant to Q6A		
Dissolution (Rev. 3)	USP	4
Disintegration (Rev. 2)	EP	1
Uniformity of Content/Mass (Rev. 2, Corr.1)	USP	4
Tests for Specified Microorganism (Rev. 1)	EP	4
Microbial Enumeration (Rev. 1, Corr. 1)	EP	4
Limits for Non-sterile Products	EP	4
Bacterial Endotoxins (Rev. 2)	JP	4
Color (instrumental method) (Rev.1)	EP	4
Extractable Volume (Rev. 1)	EP	4
Particulate Contamination (Rev. 2)	USP	1
Residue on Ignition (Rev. 2)	JP	4
Sterility Test (Rev. 1, Corr. 3)	EP	4
General Chapters		
Analytical Sieving (Rev. 1)	USP	4
Bulk Density and Tapped Density (Rev. 4)	EP	2
Conductivity (Corr. 1)	EP	4
Gas Pycnometric Density of Solids	EP	4
Powder Flow (Rev. 1)	EP	2
Tablet Friability (Rev. 1)	USP	2
Elemental Impurities	USP	2
Optical Microscopy	USP	4
Powder Fineness	USP	4
Specific Surface Area	EP	4
Laser Diffraction Measurement of Particle size (Rev. 1)	EP	1
X-Ray Powder Diffraction (Rev. 1)	EP	3A
Water-solid Interaction	EP	4
Thermal Analysis	EP	4
Chromatography	EP	2
Dynamic Light Scattering	JP	2
Methods for Biotechnology Products		
Amino Acid Determination (Rev. 1)	USP	4
Capillary Electrophoresis (Rev. 1)	EP	1
Isoelectric Focusing	EP	4
Peptide Mapping (Rev. 1)	USP	2
Polyacrylamide Gel Electrophoresis (Rev. 1)	EP	4
Monographs (Pharmaceutical Excipients)		
Alcohol (Rev. 2, Corr. 2)	EP	4
Dehydrated Alcohol (Rev. 2, Corr. 2)	EP	4
Benzyl Alcohol (Rev. 2, Corr. 1)	EP	4
Butyl Paraben (Rev. 1)	EP	4
Calcium Disodium Edetate (Rev. 1)	JP	2
Calcium Phosphate Dibasic (Rev. 1)	JP	4
Calcium Phosphate Dibasic Anhydrous (Rev. 3)	JP	4
Calcium Silicate	USP	1
Carmellose (Rev. 1)	JP	4
Carmellose Calcium (Rev. 1)	USP	4
Carmellose Sodium	USP	2
Cellulose Acetate Phthalate (Rev. 1, Corr. 1)	USP	4
Cellulose, Powdered (Rev. 1)	USP	4
Microcrystalline Cellulose (Rev. 3)	USP	4

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Citric Acid, Anhydrous (Rev. 2)	EP	4
Citric Acid, Monohydrate (Rev. 2)	EP	4
Copovidone (Rev. 1)	USP	1
Croscarmellose Sodium (Rev. 1)	USP	2
Crospovidone	EP	4
Ethylcellulose (Rev. 2)	EP	4
Ethyl Paraben (Rev. 1, Corr. 1)	JP	4
Gelatin (Rev. 3)	JP	4
Glucose Monohydrate (Corr. 1) / Anhydrous	EP	4
Glycerin	USP	1
Hydroxyethylcellulose	EP	4
Hydroxypropylcellulose	USP	4
Hydroxypropylcellulose, Low Substituted (Corr. 2)	USP	4
Hypromellose (Rev. 2)	JP	4
Hypromellose Phthalate	USP	4
Isomalt (Corr. 1)	EP	4
Isostearyl Alcohol	JP	1
Lactose, Anhydrous (Rev. 5)	USP	1
Lactose, Monohydrate (Rev. 3)	USP	1
Magnesium Stearate (Corr. 3)	USP	4
Mannitol (Corr. 1)	EP	4
Methylcellulose (Rev. 3)	JP	4
Methyl Paraben (Rev. 1, Corr. 1)	JP	4
Myristyl Myristate	JP	1
Petrolatum	USP	2
Petrolatum, White	USP	2
Polyethylene Glycol	USP	1
Polysorbate 65	JP	1
Polysorbate 80 (Corr. 3)	EP	4
Povidone (Rev. 2)	USP	1
Propylene Glycol	EP	2
Propyl Paraben (Rev. 1, Corr. 1)	JP	4
Silicon Dioxide	JP	2
Silicon Dioxide, Colloidal	JP	2
Sodium Chloride (Rev. 3, Corr. 1)	EP	4
Sodium Laurylsulfate (Rev. 1)	USP	4
Sodium Starch Glycolate (Rev. 3)	USP	4
Starch, Corn (Rev. 3)	USP	4
Starch, Potato (Rev. 2)	EP	4
Starch, Pregelatinized	JP	1
Starch, Rice (Rev. 1)	EP	4
Starch, Wheat (Rev. 3, Corr. 1)	JP	3A
Stearic Acid (Rev. 2)	EP	2
Sterile Water for Injection in Containers	USP	1
Sucrose (Rev. 1)	USP	2
Talc (Rev. 1)	EP	4

Stage 1: Preparation of first draft

Stage 2: Official Inquiry

Stage 3A: Provisional Consensus

Stage 3B: Draft Sign-off

Stage 4: Regional adoption and implementation

EP: European Pharmacopoeia

JP: Japanese Pharmacopoeia

USP: United States Pharmacopoeia