

PDG State of Work

As of August, 2021

| 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 | 2 |
| Residue on Ignition (Rev. 2) | JP | 4 |
| Sterility Test (Rev. 1, Corr. 3) | EP | 4 |
| General Chapters | | |
| Analytical Sieving (Rev. 1, Corr. 1) | JP | 1 |
| Bulk Density and Tapped Density (Rev. 4) | EP | 3A |
| Conductivity (Corr. 1) | EP | 4 |
| Gas Pycnometric Density of Solids | EP | 4 |
| Powder Flow (Rev. 1) | EP | 3A |
| Tablet Friability (Rev. 1) | USP | 2 |
| Elemental Impurities | USP | 3A |
| 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 | 3B |
| Water-solid Interaction | EP | 4 |
| Thermal Analysis | EP | 4 |
| Chromatography | EP | 3A |
| Dynamic Light Scattering | JP | 3A |
| 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. 2) | EP | 3B |
| Butyl Paraben (Rev. 1, Corr. 1) | EP | 3B |
| 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, Corr. 1) | USP | 3A |
| 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 | 3B |
| Crospovidone | EP | 4 |
| Ethylcellulose (Rev. 2) | EP | 4 |
| Ethyl Paraben (Rev. 1, Corr. 2) | EP | 3B |
| 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 (Corr. 1) | USP | 3A |
| 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. 2) | JP | 3B |
| 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. 2) | EP | 3B |
| Silicon Dioxide | JP | 2 |
| Silicon Dioxide, Colloidal | JP | 2 |
| Sodium Chloride (Rev. 3, Corr. 2) | EP | 3B |
| 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 | 3B |
| Stearic Acid (Rev. 2) | EP | 3A |
| 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