

PDG 調和活動状況

2021年8月

| 調和活動対象項目  | 担当薬局方 | ステージ |
|---|-------|------|
| <b>ICH Q6A 関連試験法</b>                                    |       |      |
| 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    |
| <b>一般試験法等</b>   |       |      |
| 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   |
| <b>バイオテクノロジー応用医薬品の試験法</b>                               |       |      |
| 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    |
| <b>各条(医薬品添加物)</b>                                       |       |      |
| 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)                  | EP    | 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    |

ステージ 1: 調和案の作成(専門家委員会検討)

ステージ 2: パブリックコメント

ステージ 3A: 調和合意案の検討

ステージ 3B: 調和合意案への署名

ステージ 4: 各薬局方の出版・施行

EP: European Pharmacopoeia

JP: Japanese Pharmacopoeia

USP: United States Pharmacopoeia