

PDG State of Work

(December 2011)

Item	Coordinating pharmacopoeia	Stage
General methods relevant to Q6A		
Dissolution (rev. 3)	USP	6
Disintegration (rev. 1)	USP	6
Uniformity of content/mass (rev. 1)	USP	6
Tests for specified microorganism (rev. 1)	EP	6
Microbial enumeration (rev. 1)	EP	6
Microbial contamination limits for non-sterile products	EP	6
Bacterial endotoxins (rev. 2)	JP	4
Color (instrumental method)	EP	3
Extractable volume of parenterals (rev. 1)	EP	6
Test for particulate contamination: subvisible particles (rev. 1)	EP	6
Residue on ignition (rev. 2)	JP	6
Sterility test (corr. 3)	EP	6
General chapters		
Analytical sieving (rev. 1)	USP	6
Bulk density and tapped density (rev. 3)	EP	4
Conductivity	USP	3 rev.1
Gas pycnometric density of solids	EP	6
Flowability (powder flow)	USP	6
Tablet friability	USP	6
Metals impurities	USP	1
Inhalation	EP	4 rev. 2
Optical microscopy	USP	6
Powder fineness	USP	6
Specific surface area	EP	6
Porosimetry by mercury intrusion	EP	6
Laser diffraction measurement of particle size	EP	6
X-ray powder diffraction	EP	6
Water-solid interaction	EP	6
Thermal analysis	EP	4 rev.
Uniformity of delivered dose of inhalation	EP	2
Calorimetry	EP	6
Density of solids	EP	6
Chromatography	EP	3

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Methods for biotechnology products		
Amino acid determination	USP	6
Capillary electrophoresis (corr. 2)	EP	6
Isoelectric focusing	EP	6
Protein determination (rev. 1)	USP	2
Peptide mapping (rev. 1)	USP	3
Polyacrylamide gel electrophoresis (rev. 1)	EP	3
Excipients		
Alcohol (rev. 2)	EP	6
Dehydrated alcohol (rev. 2)	EP	6
Benzyl alcohol (corr. 1)	EP	6
Butyl paraben (rev. 1)	EP	6
Calcium carbonate (bilateral harmonisation)	EP/JP*	3-4
Calcium disodium edetate (rev. 1)	JP	1
Calcium phosphate dibasic (and anhydrous) (rev. 1)	JP	6
Carmellose (rev. 1)	JP	6
Carmellose calcium (rev. 1)	USP	6
Carmellose sodium	USP	3 rev. 1
Cellulose acetate (rev. 2)	USP	4
Cellulose acetate phthalate (rev. 1)	USP	6
Cellulose, powdered (rev. 1)	USP	6
Citric acid, anhydrous (rev. 2)	EP	6
Citric acid, monohydrate (rev. 2)	EP	6
Copovidone	JP	4
Croscarmellose sodium	USP	6
Crospovidone	EP	6
Ethylcellulose (rev. 2)	EP	3
Ethyl paraben (corr. 1)	EP	6
Gelatin, gelling grade	EP	4 rev.
Gelatin, non-gelling grade	EP	4 rev.
Glucose monohydrate/anhydrous	EP	4 rev.
Glycerin	USP	3
Glyceryl monostearate	USP	3*
Hydroxyethylcellulose	EP	5A
Hydroxypropylcellulose	USP	4 rev.
Hydroxypropylcellulose, low substituted	USP	4 rev.
Hydroxypropylmethylcellulose (rev. 1)	JP	2
Hypromellose phthalate	USP	6
Isomalt	EP	3

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Lactose, anhydrous (rev. 5)	USP	2
Lactose for inhalation	USP	3
Lactose, monohydrate (rev. 3)	USP	2
Magnesium stearate	USP	6
Mannitol	EP	5A
Methylcellulose (rev. 2)	JP	2
Methyl paraben (corr. 1)	EP	6
Microcrystalline cellulose (rev. 1)	USP	6
Petrolatum	USP	4 rev.
Petrolatum, white	USP	4 rev.
Polyethylene glycol	USP	4 rev. 3
Polysorbate 80 (corr. 1)	EP	6
Povidone (rev. 1)	JP	3
Propylene glycol	EP	5B
Propyl paraben (corr. 1)	EP	6
Saccharin (rev. 1)	USP	3
Saccharin, calcium (rev. 1)	USP	4*
Saccharin, sodium (rev. 2)	USP	3
Silicon dioxide	JP	4 rev.
Silicon dioxide, colloidal	JP	4 rev.
Sodium chloride (rev. 3)	EP	2
Sodium laurylsulfate	USP	3 rev. 1
Sodium starch glycolate (rev. 2)	USP	2
Starch, corn (rev. 3)	USP	5A
Starch, potato (rev. 2)	EP	6
Starch, pregelatinised	JP	3
Starch, rice (rev. 1)	EP	1
Starch, wheat (rev. 2)	EP	6
Stearic acid	EP	6
Sucrose	EP	6
Talc (rev. 1)	EP	6
Titanium dioxide	JP	5A3*
Water for injection in containers	USP	3 rev. 3

* Deleted from work programme

Stage 1: Identification

Stage 2: Investigation

Stage 3: Proposal for expert committee review

Stage 4: Official inquiry

Stage 5A: Provisional consensus

Stage 5B: Draft sign-off consensus

Stage 6: Regional adoption and implementation

Stage 7: Inter-regional acceptance