

PDG State of Work

(April 2018)

Item	Coordinating pharmacopoeia	Stage
General methods relevant to Q6A		
Dissolution (rev. 3)	USP	4
Disintegration (rev. 1)	USP	4
Uniformity of content/mass (rev. 2, corr. 1)	USP	4
Tests for specified microorganisms (rev. 1)	Ph. Eur.	4
Microbial enumeration (rev. 1, corr. 1)	Ph. Eur.	4
Microbial contamination limits for non-sterile products	Ph. Eur.	4
Bacterial endotoxins (rev. 2)	JP	4
Color (instrumental method)	Ph. Eur.	3B
Extractable volume of parenterals (rev. 1)	Ph. Eur.	4
Test for particulate contamination: subvisible particles (rev. 1)	Ph. Eur.	4
Residue on ignition (rev. 2)	JP	4
Sterility test (rev. 1, corr. 3)	Ph. Eur.	4
General chapters		
Analytical sieving (rev. 1)	USP	4
Bulk density and tapped density (rev. 4)	Ph. Eur.	1
Conductivity	USP	4
Gas pycnometric density of solids	Ph. Eur.	4
Flowability (powder flow) (rev. 1)	USP	1
Tablet friability	USP	4
Metal Elemental impurities	USP	2
Inhalation *	Ph. Eur.	

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Optical microscopy	USP	4
Powder fineness	USP	4
Specific surface area	Ph. Eur.	4
Porosimetry by mercury intrusion *	Ph. Eur.	
Laser diffraction measurement of particle size (rev. 1)	Ph. Eur.	1
X-ray powder diffraction (rev. 1)	Ph. Eur.	2
Water-solid interaction	Ph. Eur.	4
Thermal analysis	Ph. Eur.	4
Uniformity of delivered dose of inhalations *	Ph. Eur.	
Microcalorimetry *	Ph. Eur.	
Density of solids (rev. 1) *	Ph. Eur.	
Chromatography	Ph. Eur.	2
Dynamic Light Scattering	JP	1
Methods for biotechnology products		
Amino acid determination (rev. 1)	USP	4
Capillary electrophoresis (corr. 2)	Ph. Eur.	4
Isoelectric focusing	Ph. Eur.	4
Protein determination (rev. 1) *	USP	
Peptide mapping (rev. 1)	USP	2
Polyacrylamide gel electrophoresis (rev. 1)	Ph. Eur.	4
Excipients		
Alcohol (rev. 2, corr 2)	Ph. Eur.	4
Dehydrated alcohol (rev. 2, corr 2)	Ph. Eur.	4
Benzyl alcohol (rev. 2, corr 1)	Ph. Eur.	4
Butyl paraben (rev. 1)	Ph. Eur.	4

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Calcium carbonate *	JP	
Calcium disodium edetate (rev. 1)	JP	2
Calcium phosphate dibasic (anhydrous) (rev. 3)	JP	2
Calcium phosphate dibasic (rev. 1)	JP	4
Carmellose (rev. 1)	JP	4
Carmellose calcium (rev. 1)	USP	4
Carmellose sodium	USP	1
Cellulose acetate (rev. 3) *	USP	
Cellulose acetate phthalate (rev. 1, corr. 1)	USP	4
Cellulose, powdered (rev. 1)	USP	4
Citric acid, anhydrous (rev. 2)	Ph. Eur.	4
Citric acid, monohydrate (rev. 2)	Ph. Eur.	4
Copovidone	JP	2
Croscarmellose sodium	USP	4
Crospovidone	Ph. Eur.	4
Ethylcellulose (rev. 2)	Ph. Eur.	4
Ethyl paraben (rev. 1, corr. 1)	Ph. Eur.	4
Gelatin, gelling grade (rev. 2)	Ph. Eur.	2
Gelatin, non-gelling grade (rev. 2)	Ph. Eur.	2
Glucose monohydrate/anhydrous (corr. 1)	Ph. Eur.	4
Glycerin	USP	1
Hydroxyethylcellulose	Ph. Eur.	4
Hydroxypropylcellulose	USP	4
Hydroxypropylcellulose, low substituted (corr. 2)	USP	4
Hypromellose (rev. 2)	JP	4

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Hypromellose phthalate	USP	4
Isomalt (rev. 1, corr. 1)	Ph. Eur.	4
Lactose, anhydrous (rev. 5)	USP	1
Lactose for inhalation	USP	1
Lactose, monohydrate (rev. 3)	USP	1
Magnesium stearate (corr. 3)	USP	4
Mannitol (corr. 1)	Ph. Eur.	4
Methylcellulose (rev. 3)	JP	4
Methyl paraben (rev. 1, corr. 1)	JP	4
Microcrystalline cellulose (rev. 2)	USP	4
Petrolatum	USP	2
Petrolatum, white	USP	2
Polyethylene glycol	USP	2
Polysorbate 80 (corr. 3)	Ph. Eur.	4
Povidone (rev. 1, corr. 1)	JP	4
Propylene glycol	Ph. Eur.	2
Propyl paraben (rev. 1, corr. 1)	Ph. Eur.	4
Saccharin (rev. 1) *	USP	
Saccharin, calcium (rev. 1) *	USP	
Saccharin, sodium (rev. 2) *	USP	
Silicon dioxide	JP	2
Silicon dioxide, colloidal	JP	2
Sodium chloride (rev. 3, corr. 1)	Ph. Eur.	4
Sodium laurylsulfate (rev. 1)	USP	2
Sodium starch glycolate (rev. 2)	USP	4

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Starch, corn (rev. 3)	USP	4
Starch, potato (rev. 2)	Ph. Eur.	4
Starch, pregelatinised	JP	1
Starch, rice (rev. 1)	Ph. Eur.	4
Starch, wheat (rev. 3)	Ph. Eur.	2
Stearic acid (rev. 1, corr. 1)	Ph. Eur.	4
Sucrose	Ph. Eur.	4
Talc (rev. 1)	Ph. Eur.	4
Water for injection in containers	USP	2

*Deleted from work programme: bilateral harmonisation

Stage 1: preparation of first draft	Stage 3B: Draft sign-off
Stage 2: Official inquiry	Stage 4: Regional adoption and implementation
Stage 3A: Provisional consensus	Stage 5: Inter-regional acceptance (for ICH Q4B items)