

PDG 調和文書 収載 (試験法)

2015年7月1日

調和項目	署名日	Stage 6A			Stage 6B			Stage 6C		
		採用・公開(告示)			施行			調和状況の公開(参考情報)		
		EP	JP	USP	EP	JP	USP	EP	JP	USP
Dissolution	Jun. 22, 2004	2005/06	Mar. 31, 2006	2005.03.31	Jan. 1, 2006	Apr. 1, 2006	2006.04.01	—	Apr. 1, 2006	2006.04.01
Rev. 1	Nov. 8, 2005	—	—	—	—	—	—	—	—	—
Rev. 2	Nov. 12, 2008	2009/06	Jul. 30, 2010	2010.04.01	Jan. 1, 2010	Jul. 30, 2010	2010.10.01	—	Jul. 30, 2010	2010.10.01
Rev. 3	Jun. 10, 2010	2010/11	Sep. 27, 2012	2011.02.25	Jan. 1, 2016	Oct. 1, 2012	2011.12.01	Jan. 1, 2016	Oct. 1, 2012	2011.12.01
Disintegration	Jun. 21, 2004	2005/06	Mar. 31, 2006	2005.03.31	Jan. 1, 2006	Apr. 1, 2006	—	—	Apr. 1, 2006	2006.04.01
Rev. 1	Oct. 30, 2007	2008/06	Mar. 2009	2008.06.06	Jan. 1, 2009	Mar. 2009	2008.08.01	Apr. 1, 2011	Mar. 2009	2008.08.01
Uniformity of Content/ Mass	Feb. 18, 2004	2004/12	Mar. 31, 2006	2010.04.01	Jun. 1, 2005	Apr. 1, 2006	2010.10.01	—	Apr. 1, 2006	2010.10.01
Rev. 1	Nov. 9, 2010	2011/03	May 31, 2013	2011.02.25	Apr. 1, 2012	May 31, 2013	2011.12.01	—	May 31, 2013	2011.12.01
Revision: Sign-off cover sheet	Jun. 15, 2011	—	—	—	—	—	—	Jan. 1, 2016	—	—
Revision: Sign-off cover sheet	Nov. 6, 2013	—	—	—	—	—	—	—	—	—
Tests for Specified Microorganisms	Nov. 8, 2005	2006/06	Sep. 28, 2007	2006.08.01	Jan. 1, 2007	Oct. 1, 2007	—	—	Oct. 1, 2007	—
Rev. 1	Jun. 5, 2008	2008/12	Mar. 2009	2010.04.01	Jul. 1, 2009	Mar. 2009	2010.10.01	Apr. 1, 2010	Mar. 2009	2010.10.01
Microbiological Enumeration	Nov. 8, 2005	2006/06	Sep. 28, 2007	2006.08.01	Jan. 1, 2007	Oct. 1, 2007	—	—	Oct. 1, 2007	—
Rev. 1	Jun. 5, 2008	2008/12	Mar. 2009	2010.04.01	Jul. 1, 2009	Mar. 2009	2010.10.01	—	Mar. 2009	2010.10.01
Corr. 1	Jun. 10, 2009	2009/06	Mar. 24, 2011	2010.07.01	—	Apr. 1, 2011	—	Jul. 1, 2010	Apr. 1, 2011	—
Microbial Contamination Limits for Non-sterile Products	Nov. 8, 2005	2006/06	Sep. 28, 2007	2008.11.01	Mar. 1, 2009	Oct. 1, 2007	2009.05.01	Apr. 1, 2010	Oct. 1, 2007	2009.05.01
Rev. 1	Jun. 27, 2013	—	—	—	—	—	—	—	—	—
Bacterial Endotoxins	Jan. 3, 2000	2006/06	Mar. 30, 2001	2000.07.31	Jan. 1, 2001	Apr. 1, 2001	2002.01.01	—	Apr. 1, 2006	2002.01.01
Rev. 1	Nov. 11, 2008	2009/06	Mar. 24, 2011	2010.04.01	Jan. 1, 2010	Apr. 1, 2011	2010.10.01	—	Apr. 1, 2011	2010.10.01
Corr. 1	Oct. 27, 2009	2009/11	Mar. 24, 2011	2011.04.01	—	Apr. 1, 2011	2011.10.01	—	Apr. 1, 2011	2011.10.01
Rev. 2	Jun. 15, 2011	—	Sep. 27, 2012	2011.11.23	—	Oct. 1, 2012	2012.12.01	—	Oct. 1, 2012	2012.12.01
Extractable Volume of Parenterals	Jul. 18, 2000	2001/06	—	2000.07.31	Jan. 1, 2002	—	2002.01.01	—	—	2002.01.01
Rev. 1	Jun. 10, 2004	2005/06	Jul. 21, 2005	2006.11.14	—	Jul. 21, 2005	2006.11.14	Apr. 1, 2010	Jul. 21, 2005	2006.11.14
Revision: Sign-off cover sheet	Nov. 9, 2010	—	—	—	—	—	—	—	—	—
Particulate Matter in Injectables	May 21, 2001	2002/06	—	2001.03.31	Jan. 1, 2003	—	2002.01.01	—	—	2002.01.01
Rev. 1	Jun. 10, 2004	—	Mar. 31, 2006	2007.03.01	—	Apr. 1, 2006	2007.04.01	—	Apr. 1, 2006	2007.08.01
Revision: Sign-off cover sheet	Nov. 9, 2010	—	Mar. 24, 2011	—	—	Apr. 1, 2011	—	Apr. 1, 2011	Apr. 1, 2011	—
Update to Rev. 1	Jun. 6, 2012	N/A	—	—	—	—	—	—	—	—
Sulphated Ash/ Residue on Ignition	Feb. 11, 2000	2001/06	Dec. 27, 2002	2002.11.01	Jan. 1, 2002	Jan. 1, 2003	—	—	—	—
Rev. 1	Sep. 10, 2002	—	Dec. 28, 2004	2006.02.01	—	Jan. 1, 2005	2006.04.01	—	—	2006.04.01
Rev. 2	Aug. 4, 2005	2005/06	Mar. 31, 2006	2006.02.01	Jan. 1, 2006	Apr. 1, 2006	2006.08.01	Apr. 1, 2010	Apr. 1, 2006	2006.08.01
Sterility	Sep. 10, 2002	2003/06	Dec. 28, 2004	2003.05.01	Jan. 1, 2004	Jan. 1, 2005	2004.01.01	—	Apr. 1, 2006	2004.01.01
Rev. 1	Oct. 30, 2007	2008/06	Mar. 2009	2009.02.01	Jan. 1, 2009	Mar. 2009	2009.08.01	—	Mar. 2009	2009.08.01
Corr. 1	Jun. 3, 2008	2008/06	Mar. 2009	2009.02.01	Jan. 1, 2009	Mar. 2009	2009.08.01	—	Mar. 2009	2009.08.01
Corr. 2	Nov. 11, 2008	—	—	—	—	—	—	—	—	—
Corr. 3	Jun. 10, 2009	2009/06	Mar. 24, 2011	2010.07.01	—	Apr. 1, 2011	—	Apr. 1, 2011	Apr. 1, 2011	—
Analytical Sieving	Jun. 10, 2004	—	Mar. 31, 2006	2005.09.01	Jan. 1, 2006	Apr. 1, 2006	2005.09.01	—	Apr. 1, 2006	2005.09.01
Rev. 1	May 8, 2007	2008/01	Sep. 30, 2009	2009.06.01	Jul. 1, 2008	Oct. 1, 2009	2009.12.01	Jan. 1, 2010	Oct. 1, 2009	2009.12.01
Bulk and Tapped Density of Solids	May 8, 2007	2008/01	Sep. 30, 2009	2009.08.01	Jul. 1, 2008	Oct. 1, 2009	2009.08.01	—	Oct. 1, 2009	2009.08.01
Rev. 1	Jun. 5, 2008	2008/12	Sep. 30, 2009	2010.04.01	Jul. 1, 2009	Oct. 1, 2009	2010.10.01	—	Oct. 1, 2009	2010.10.01
Corr. 1	Jun. 10, 2009	2009/06	Mar. 24, 2011	2011.02.11	Jul. 1, 2010	Apr. 1, 2011	2011.08.01	—	Apr. 1, 2011	2011.08.01
Rev. 2	Jun. 15, 2011	2011/11	Sep. 27, 2012	2011.11.23	Jan. 1, 2013	Oct. 1, 2012	2012.12.01	—	Oct. 1, 2012	2012.10.01
Rev. 3	Nov. 6, 2013	2014/06	Sep. 27, 2012	2014.09.26	Jul. 1, 2015	Oct. 1, 2012	(Aug. 1, 2015)	—	Oct. 1, 2012	—
Gas Pycnometric Density of Solids	May 8, 2007	2008/01	Sep. 30, 2009	2009.08.01	Jul. 1, 2008	Oct. 1, 2009	2009.08.01	—	Oct. 1, 2009	2009.08.01
Flowability (Powder Flow)	Jun. 10, 2004	2005/06	Mar. 31, 2006	2005.06.01	Jan. 1, 2006	Apr. 1, 2006	2005.08.01	Jan. 1, 2010	Apr. 1, 2006	2005.08.01
Tablet Friability	Feb. 18, 2004	2004/12	Mar. 31, 2006	2006.03.01	Jul. 1, 2005	Apr. 1, 2006	2006.08.01	Jan. 1, 2010	Apr. 1, 2006	2006.08.01
Optical Microscopy	Jun. 10, 2004	2005/06	Mar. 31, 2006	2005.06.01	Jan. 1, 2006	Apr. 1, 2006	2005.12.01	Jan. 1, 2010	Apr. 1, 2006	2005.12.01
Powder Fineness	May 8, 2007	2008/01	Sep. 30, 2009	2011.11.01	Jul. 1, 2008	Oct. 1, 2009	2012.05.01	—	Oct. 1, 2009	2012.05.01
Specific Surface Area	Nov. 10, 2003	2004/09	Mar. 31, 2006	2005.05.01	Apr. 1, 2005	Apr. 1, 2006	2005.04.01	Jan. 1, 2010	Apr. 1, 2006	2005.04.01
Porosimetry by Mercury Intrusion	May 8, 2007	2008/01	—	2011.11.01	Jul. 1, 2008	—	2012.05.01	—	—	2012.05.01
Laser diffraction measurement of particle size	Nov. 11, 2008	2009/06	Mar. 24, 2011	2010.04.01	Jan. 1, 2010	Apr. 1, 2011	2010.10.01	—	Apr. 1, 2011	2010.10.01

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		EP	JP	USP	EP	JP	USP	EP	JP	USP
X-Ray Powder Diffraction	Oct. 30, 2007	2008/06	Mar. 24, 2011	2010.04.01	Jan. 1, 2009	Apr. 1, 2011	2010.10.01	—	Apr. 1, 2011	2010.10.01
Water-solid Interactions	Oct. 27, 2009	2010/03	Sep. 27, 2012	2011.06.01	Apr. 1, 2011	Oct. 1, 2012	2011.12.01	—	Oct. 1, 2012	2011.12.01
Thermal Analysis	Jun. 26, 2014	(2014/11)	(Mar, 2016)		Jan. 1, 2016	(Apr, 2016)		Jan. 1, 2016	(Apr, 2016)	
Microcalorimetry	Jun. 15, 2011		—	2012.02.29		—	2012.12.01		—	2012.12.01
Amino Acid Determination	Sep. 9, 2002	2003/06	Dec. 28, 2004	2009.01.01	2005/01	Jan. 1, 2005	2009.02.01	Jan. 1, 2010	Apr. 1, 2006	2009.02.01
Capillary Electrophoresis	Sep. 10, 2002	2003/06	Dec. 28, 2004	2009.05.21	2005/01	Jan. 1, 2005	2009.07.01	Jan. 1, 2010	Apr. 1, 2006	2009.11.01
Corr. 1	Oct. 27, 2009		—	2010.11.01		—	2011.05.01	—	—	2011.05.01
Corr. 2	Jun. 9, 2010	2010/06	Jul. 20, 2010	2010.10.01		Jul. 20, 2010	2011.02.01	—	Jul. 20, 2010	2011.02.01
Isoelectric Focusing	Sep. 9, 2002	2003/06	Dec. 28, 2004	2009.05.21	2004/01	Jan. 1, 2005	2009.07.01	Jan. 1, 2010	Apr. 1, 2006	2009.11.01
Protein Determination	Sep. 10, 2002	2003/06	Dec. 28, 2004	2007.02.01	2004/01	Jan. 1, 2005	2007.08.01	—	Apr. 1, 2006	2007.08.01
Peptide Mapping	Sep. 10, 2002	2003/06	Dec. 28, 2004	2009.05.21	2004/01	Jan. 1, 2005	2009.07.01	Jan. 1, 2010	Apr. 1, 2006	2009.11.01
Polyacrylamide Gel Electrophoresis	Oct. 15, 1999	2001/09	Dec. 27, 2002	2009.06.01	2002/01	Jan. 1, 2003	2009.12.01	—	Apr. 1, 2006	2009.12.01
Rev. 1	Jun. 26, 2014		(Mar, 2016)	2014.11.21		(Apr, 2016)	(Dec. 1, 2015)	Jan. 1, 2010	(Apr, 2016)	