JP15 table of errata

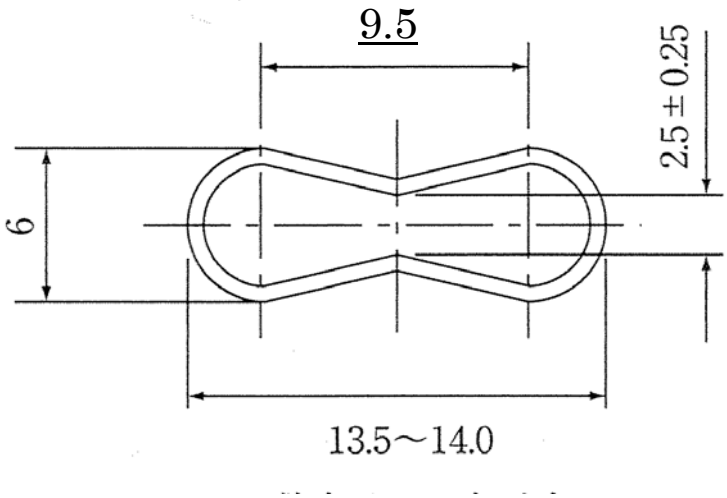
November 5, 2008

page	line	correction	error
76 right	↓ 29	Methods using mechanical agitation or electromagnetic agitation, and that can induce either a vertical oscillation or a horizontal circular motion, or tapping or a combination of both tapping and horizontal circular motion are available.	Methods using mechanical agitation or electromagnetic agitation, and that can include either a vertical oscillation or a horizontal circular motion, or tapping or a combination of both tapping and horizontal circular motion are available.
107 left	↑ 14	**Liquid dosage forms**－Assay 10 units individually using an appropriate analytical method. Carry out the assay on the amount of well-mixed material that is removed from an individual container in conditions of normal use and express the results as delivered dose.	**Liquid dosage forms**－Carry out the assay on the amount of well-mixed material that is removed from an individual container in conditions of normal use and express the results as delivered dose.
111 left	↓ 14	However, it may be necessary to test some preparations by Method 1 followed by Method 2 to reach a conclusion on conformance to the requirements.	However, it may be necessary to test some preparations by Method 2 followed by Method 1 to reach a conclusion on conformance to the requirements.
118 left	Fig6.10-4	attachment	attachment
502 left	↓ 13	Mobile phase: Dissolve 8.57g of ammonium dihydrogen phosphate and 1 ml of phosphoric acid in water to make 1000ml. To 800ml of this solution add 200ml of acetonitrile.	Mobile phase: Dissolve 8.57g of ammonium dihydrogen phosphate and 1 ml of phosphoric acid in water to make 1000ml. To 800ml of this solution add 200ml of acetic acid.
639 left	↑ 14	Separately, to 100 μL of anhydrous methanol add Anhydrous Ethanol to make exactly 50 mL.	Separately, to 100 μL of anhydrous ethanol add Anhydrous Ethanol to make exactly 50 mL.
738 left	↑ 4	Prepare the control solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.355%).	Prepare the control solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.335%).
1370 left	↓ 26	Uncaria Hook contains not less than 0.03% of total alkaloids (rhynchophylline and hirsutine), calculated on the dried basis.	Uncaria Hook contains not less than 0.03% of total alkaloids (rhynchophylline and hirstine), calculated on the dried basis.
1370 right	↓ 28	Amount (mg) of total alkaloids (rhynchophylline and hirsutine)	Amount (mg) of total alkaloids (rhynchophylline and hirstine)
1675 right	↑ 23	$N = \frac{(\mu ep + \mu eo) \times V \times l}{2 \times D \times L}$	$N = \frac{(\mu ep + \mu eo) \times V \times L}{2 \times D \times L}$
1739 right	↓ 5	3.5.1 Monitoring of Electrical Conductivity as the Indicator for inorganic impurities	3.5.1 Monitoring with an Indicator of Electrical Conductivity
1740 right	↑ 32	3.5.2 Monitoring of Total Organic Carbon (TOC) as the Indicator for organic impurities The limit of total organic carbon (TOC) for *Water for Injection* produced by ultrafiltration and/or reverse osmosis has been specified as "not greater than 500ppb"; however it is strongly desirable for each facility producing pharmaceutical water to conduct operation control of pharmaceutical water systems through TOC monitoring on produced water based on its own alert and action levels for TOC determined individually. The followings are the recommended action levels for TOC.	3.5.2 Monitoring with an Indicator of Total Organic Carbon (TOC) Drinking Water Standards (Prescribed under the Article 4 of the Japanese Water Supply Law) require that TOC should be "not greater than 5 ppm". However, it is preferable for individual facilities to conduct TOC monitoring on *Water* with alter and action levels separately determined for water-quality control by TOC monitoring.

		・Action Level: ≦300ppb (in-line) ≧400ppb (off-line) Drinking Water Standards (Prescribed under the Article 4 of the Japanese Water Supply Law) require that TOC should be "not greater than 5 ppm." However taking the recommended action levels described above into consideration, it is also desirable for each facility to conduct water-quality control through TOC monitoring on source water based on its own alert and action levels for TOC determined individually.	
1751 right	↑ 28	Use a drum, with an internal diameter between 283 and 291 mm and a depth between 36 and 40 mm, of transparent synthetic polymer with polished internal surface, and subject to minimum static build-up (see figure for a typical apparatus).	Use a drum, with an internal diameter between 283 and 291 mm and a depth between 36 and 40 mm, of transparent synthetic polymer with polished internal surface, and not subject to minimum static build-up (see figure for a typical apparatus).
1751 right	↑ 4	A maximum mean weight loss from the three samples of not more than 1.0% is considered acceptable for most products.	A maximum mean weight loss from the three samples of not more than 1% is considered acceptable for most products.

attachment

correction :



error :