

# JP15 table of errata

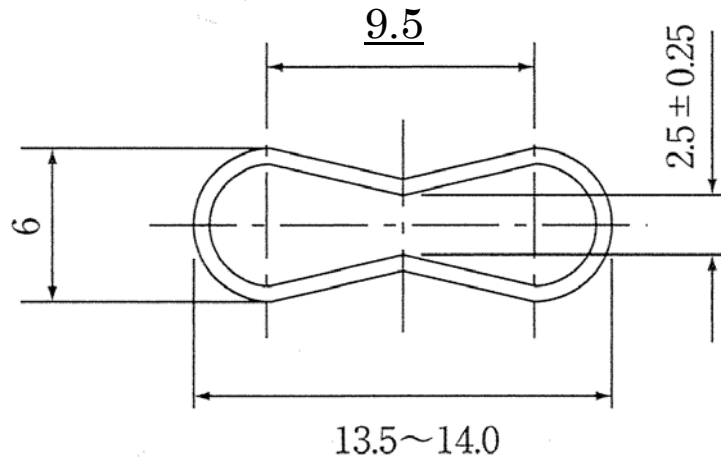
November 5, 2008

page	line	correction	error
76 right	↓ 29	Methods using mechanical agitation or electromagnetic agitation, and that can <u>induce</u> 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 <u>include</u> 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	<b>Liquid dosage forms – Assay</b> <u>10 units individually using an appropriate analytical method.</u> 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.	<b>Liquid dosage forms</b> – 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 <u>1</u> followed by Method <u>2</u> to reach a conclusion on conformance to the requirements.	However, it may be necessary to test some preparations by Method <u>2</u> followed by Method <u>1</u> 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 <u>acetonitrile</u> .	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 <u>acetic acid</u> .
639 left	↑ 14	Separately, to 100 μL of anhydrous <u>methanol</u> add Anhydrous Ethanol to make exactly 50 mL.	Separately, to 100 μL of anhydrous <u>ethanol</u> 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 <u>0.355%</u> ).	Prepare the control solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS (not more than <u>0.335%</u> ).
1370 left	↓ 26	Uncaria Hook contains not less than 0.03% of total alkaloids (rhynchophylline and <u>hirsutine</u> ), calculated on the dried basis.	Uncaria Hook contains not less than 0.03% of total alkaloids (rhynchophylline and <u>hirstine</u> ), calculated on the dried basis.
1370 right	↓ 28	Amount (mg) of total alkaloids (rhynchophylline and <u>hirsutine</u> )	Amount (mg) of total alkaloids (rhynchophylline and <u>hirstine</u> )
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 <u>of Electrical Conductivity as the Indicator for inorganic impurities</u>	3.5.1 Monitoring <u>with an Indicator of Electrical Conductivity</u>
1740 right	↑ 32	3.5.2 Monitoring <u>of Total Organic Carbon (TOC) as the Indicator for organic impurities</u> <u>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.</u>	3.5.2 Monitoring <u>with an Indicator of Total Organic Carbon (TOC)</u> 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, <u>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.</u>

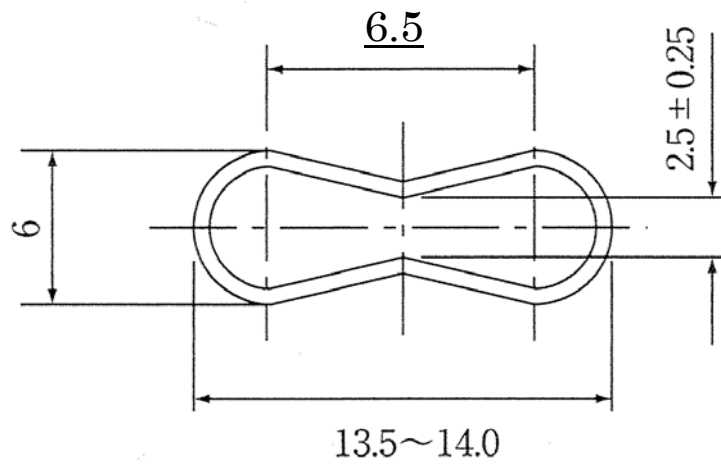
		<p>• Action Level: <math>\leq 300</math>ppb (in-line)  <math>\geq 400</math>ppb (off-line)</p> <p>Drinking Water Standards (Prescribed under the Article 4 of the Japanese Water Supply Law) require that TOC should be “not greater than 5 ppm.” However <u>taking the recommended action levels described above 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.</u></p>	
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 <u>not</u> 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 <u>1.0</u> % is considered acceptable for most products.	A maximum mean weight loss from the three samples of not more than <u>1</u> % is considered acceptable for most products.

attachment

correction :

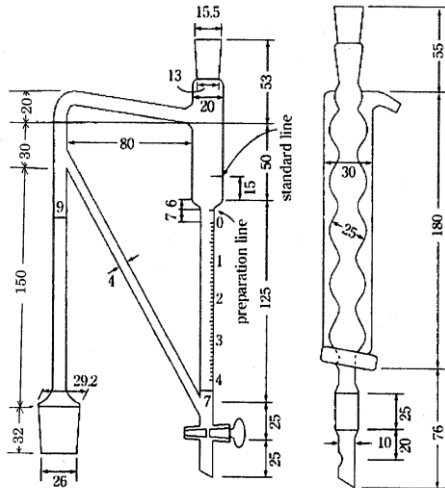
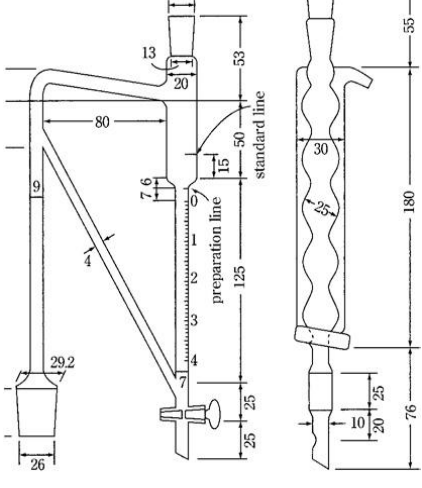


error :



page	line	correction	error
1014 right	↑ 20	<u>a thick, opalescent mucilage</u> is formed.	<u>a subtle white-turbid, pasty liquid</u> is formed.
1237 right	↓ 19	<u>a thin, cloudy mucilage</u> is formed.	<u>a subtle white-turbid, pasty liquid</u> is formed.
1675 right	↑ 6	$\bar{\mu}_{ep} = \frac{1}{2} (\mu_{epb} + \underline{\mu_{epa}}).$	$\bar{\mu}_{ep} = \frac{1}{2} (\mu_{epb} + \underline{\mu_{epa}}).$
1678 left	↓ 5	$\underline{\Delta pI} = 3 \sqrt{\frac{D(dpH/dx)}{E(-d\mu/dpH)}}$	$\underline{\Delta PI} = 3 \sqrt{\frac{D(dpH/dx)}{E(-d\mu/dpH)}}$

July 20, 2010

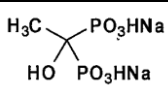
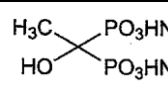
page	line	correction	error
50 left	↑ 17	Catholyte for water determination — Dissolve 25 g of lithium chloride in 1000 mL of a mixture of methanol for water determination and nitroethane (4 : 1).	Catholyte for water determination — Dissolve 25 g of lithium chloride in 1000 mL of a mixture of methanol for water determination and nitromethane (4 : 1).
59 right	↓ 7	<u>Pulverize potassium dihydrogen phosphate for pH determination and dry at 110°C to constant mass. Pulverize disodium hydrogen phosphate for pH determination and dry at 110°C to constant mass. Weigh 3.40 g (0.025 mole) of the pulverized and dried potassium dihydrogen phosphate and 3.55 g (0.025 mole) of the pulverized and dried disodium hydrogen phosphate accurately, and dissolve in water to make exactly 1000 mL.</u>	<u>Pulverize potassium dihydrogen phosphate for pH determination and disodium hydrogen phosphate for pH determination, and dry at 110°C to constant mass. Weigh 3.40 g (0.025 mole) of potassium dihydrogen phosphate and 3.55 g (0.025 mole) of disodium hydrogen phosphate dodecahydrate accurately, and dissolve in water to make exactly 1000 mL.</u>
61 right	↑ 17	$\rho_T^r = \rho_{S1}^r d_T^r$	$\rho_T^r = \rho_{S1}^r d_T^r$
99 right	Fig. 5.01-1	 <p>The figures are in mm.</p>	 <p>The figures are in mm.</p>
123 left	↓ 22	(iii) Potassium permanganate-reducing substances: Place <u>20.0</u> mL of the test solution in a glass-stoppered, conical flask,	(iii) Potassium permanganate-reducing substances: Place <u>20</u> mL of the test solution in a glass-stoppered, conical flask,
135 right	↓ 23	Each mL of 1 mol/L hydrochloric acid VS = <u>53.00</u> mg of Na <sub>2</sub> CO <sub>3</sub>	Each mL of 1 mol/L hydrochloric acid VS = <u>52.99</u> mg of Na <sub>2</sub> CO <sub>3</sub>
135 right	↑ 5	<u>Preparation</u> — Before use, dilute 0.2 mol/L hydrochloric acid VS with water to make exactly twice the initial volume. <u>Each mL of 0.1 mol/L hydrochloric acid VS = 5.300 mg of Na<sub>2</sub>CO<sub>3</sub></u>	<u>Preparation</u> — Before use, dilute 0.2 mol/L hydrochloric acid VS with water to make exactly twice the initial volume.

141 left	↑ 17	Each mL of 0.02 mol/L sodium tetraphenylborate VS = <u>7.166</u> mg of KB (C <sub>6</sub> H <sub>5</sub> ) <sub>4</sub>	Each mL of 0.02 mol/L sodium tetraphenylborate VS = <u>7.167</u> mg of KB (C <sub>6</sub> H <sub>5</sub> ) <sub>4</sub>
142 left	↓ 6	Each mL of 0.5 mol/L sulfuric acid VS = <u>53.00</u> mg of Na <sub>2</sub> CO <sub>3</sub>	Each mL of 0.5 mol/L sulfuric acid VS = <u>52.99</u> mg of Na <sub>2</sub> CO <sub>3</sub>
142 left	↑ 14	Each mL of 0.05 mol/L sulfuric acid VS = <u>5.300</u> mg of Na <sub>2</sub> CO <sub>3</sub>	Each mL of 0.05 mol/L sulfuric acid VS = <u>5.299</u> mg of Na <sub>2</sub> CO <sub>3</sub>
158 right	↑ 8	as directed in the Identification (4) under Hochuekkito Extract: no spot appears other than the principal spot of around Rf <u>0.4</u> .	as directed in the Identification (4) under Hochuekkito Extract: no spot appears other than the principal spot of around Rf <u>0.5</u> .
164 right	↑ 28	Dissolve 50 mg of bromocresol green in 0.72 mL of 0.1 mol/L sodium hydroxide VS <u>and 20 mL of ethanol (95)</u> .	Dissolve 50 mg of bromocresol green in 0.72 mL of 0.1 mol/L sodium hydroxide VS <u>and ethanol (95)</u> .
180 left	↓ 22	Each mL of 0.1 mol/L silver nitrate VS = <u>9.853</u> mg of C <sub>6</sub> H <sub>8</sub> N <sub>2</sub> O.2HCl	Each mL of 0.1 mol/L silver nitrate VS = <u>9.854</u> mg of C <sub>6</sub> H <sub>8</sub> N <sub>2</sub> O.2HCl
187 right	↑ 3	Each mL of 0.05 mol/L perchloric acid VS = <u>16.39</u> mg of C <sub>21</sub> H <sub>25</sub> N.HCl	Each mL of 0.05 mol/L perchloric acid VS = <u>16.40</u> mg of C <sub>21</sub> H <sub>25</sub> N.HCl
193 left	↑ 9	<i>Clarity and color of solution:</i> Dissolve <u>71</u> <i>nkats</i> <sub>s-2222</sub> of it in 10 mL water;	<i>Clarity and color of solution:</i> Dissolve <u>7</u> <i>lnkats</i> <sub>s-2222</sub> of it in 10 mL water;
193 left	↑ 4	<b>Factor Xa TS</b> Dissolve <u>71</u> <i>nkats</i> <sub>s-2222</sub> of factor Xa in 10 mL of water.	<b>Factor Xa TS</b> Dissolve <u>7</u> <i>lnkats</i> <sub>s-2222</sub> of factor Xa in 10 mL of water.
197 left	↑ 17	<b>7-(Glutaryl-glycyl-L-arginylamino)-4-methylcoumarin TS</b> Dissolve 5 mg of 7-(glutaryl-glycyl-L-arginyl-amino)-4-methylcoumarin in 0.5 to 1 mL of acetic acid (100), lyophilize, dissolve this in 1 mL of dimethyl- sulfoxide, and use this solution as solution A. Dissolve 30.0 g of 2-amino-2-hydroxymethyl-1,3-propanediol and 14.6 g of sodium chloride in 400 mL of water, adjust the pH to 8.5 with dilute hydrochloric acid, add water to make 500 mL, and use this solution as solution B. Mix 1 mL of the solution A and 500 mL of the solution B before use. <b>Glutathion</b> C <sub>10</sub> H <sub>17</sub> N <sub>3</sub> O <sub>6</sub> S [Same as the namesake monograph]	<b>7-(Glutaryl-glycyl-L-arginylamino)-4-methylcoumarin TS</b> Dissolve 5 mg of 7-(glutaryl-glycyl-L-arginyl-amino)-4-methylcoumarin in 0.5 to 1 mL of acetic acid (100), lyophilize, dissolve this in 1 mL of dimethyl- sulfoxide, and use this solution as solution A. Dissolve 30.0 g of 2-amino-2-hydroxymethyl-1,3-propanediol and 14.6 g of sodium chloride in 400 mL of water, adjust the pH to 8.5 with dilute hydrochloric acid, add water to make 500 mL, and use this solution as solution B. Mix 1 mL of the solution A and 500 mL of the solution B before use.
203 left	↓ 5	<b>N-(3-Hydroxyphenyl)acetamide</b> C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub>	<b>N-(3-Hydroxyphenyl)acetamide</b> C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub>
212 left	↑ 4	0.100 g of magnesium sulfate <u>hepta</u> hydrate,	0.100 g of magnesium sulfate hydrate,
217 right	↑ 15	System performance: When the procedure is run with <u>10</u> µL of the standard solution under the above operating conditions,	System performance: When the procedure is run with <u>20</u> µL of the standard solution under the above operating conditions,
219 right	↑ 23	<b>Naringin for thin-layer chromatography</b> C <sub>27</sub> H <sub>32</sub> O <sub>14</sub> .2H <sub>2</sub> O	<b>Naringin for thin-layer chromatography</b> C <sub>27</sub> H <sub>32</sub> N <sub>14</sub> .2H <sub>2</sub> O

221 right	↓ 14	<p><b>Nitrogen monoxide</b> NO A colorless gas. Prepare by adding sodium nitrite TS to a solution of iron (II) sulfate heptahydrate in dilute sulfuric acid. Nitrogen monoxide from a metal cylinder may be used.</p> <p><b>Nitroethane</b> C<sub>2</sub>H<sub>5</sub>NO<sub>2</sub>  <u>Density &lt;2.56&gt;: 1.048 – 1.053 g/cm<sup>3</sup> at 20°C</u>  <u>Water &lt;2.48&gt;: less than 0.1%.</u></p>	<p><b>Nitrogen monoxide</b> NO A colorless gas. Prepare by adding sodium nitrite TS to a solution of iron (II) sulfate heptahydrate in dilute sulfuric acid. Nitrogen monoxide from a metal cylinder may be used.</p>
252 left	↑ 23	<p><b>Thioacetamide-alkaline glycerin TS</b> To 0.2 mL of thioacetamide TS add 1 mL of alkaline glycerin TS, and heat for 20 <u>seconds</u> in a water bath. Prepare before use.</p>	<p><b>Thioacetamide-alkaline glycerin TS</b> To 0.2 mL of thioacetamide TS add 1 mL of alkaline glycerin TS, and heat for 20 <u>minutes</u> in a water bath. Prepare before use.</p>
263 left	↑ 14	<p>(2) Semimicrobalances — Use balances readable to the extent of <u>10 µg</u>.</p>	<p>(2) Semimicrobalances — Use balances readable to the extent of <u>0.01 mg</u>.</p>
263 left	↑ 12	<p>(3) Microbalances—Use balances readable to the extent of <u>1 µg</u>.</p>	<p>(3) Microbalances—Use balances readable to the extent of <u>0.001 mg</u>.</p>
264	Table 9.63 No. 6 Maximum scale error at any point	<p>0.4°C (<u>0.3°C, at 245°C of test temperature;</u> 0.5°C, at 315°C of test temperature)</p>	<p>0.4°C (0.5°C, at 315°C of test temperature)</p>
272 left	↓ 10	[75443-99-1]	[75443-99-0]
281 right	↑ 27	<p><i>Internal standard solution</i> — A solution of propyl parahydroxybenzoate in methanol (<u>1 in 2,000</u>).</p>	<p><i>Internal standard solution</i> — A solution of propyl parahydroxybenzoate in methanol (<u>3 in 20,000</u>).</p>
303 right	↓ 5	<p>(1R,3S,5R,6R,9R, 11R, 15S, 16R, 17R, 18S, 19E, 21E, 23E,25E,27E,29E,31E,33R,35S,<u>36R</u>,37S)-33-(3-Amino-3,6-dideoxy-β-D-mannopyranosyloxy)-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid</p>	<p>(1R,3S,5R,6R,9R, 11R, 15S, 16R, 17R, 18S, 19E, 21E, 23E,25E,27E,29E,31E,33R,35S,<u>36S</u>,37S)-33-(3-Amino-3,6-dideoxy-β-D-mannopyranosyloxy)-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid</p>
305 left	↓ 9	Storage — <u>Light resistant, and in a cold place.</u>	Storage — <u>Store in a cold place.</u>
310 left	↓ 10	Each mL of 0.1 mol/L silver nitrate VS = <u>35.15</u> mg of C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub>	Each mL of 0.1 mol/L silver nitrate VS = <u>35.14</u> mg of C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub>
310 right	↑ 2	Each mL of 0.05 mol/L iodine VS = <u>9.412</u> mg of C <sub>11</sub> H <sub>12</sub> N <sub>2</sub> O	Each mL of 0.05 mol/L iodine VS = <u>9.411</u> mg of C <sub>11</sub> H <sub>12</sub> N <sub>2</sub> O

343 left	↑ 28	It contains more than 50.0 % and not more than 55.0 % of benzalkonium chloride (C <sub>22</sub> H <sub>40</sub> ClN: 354.01).	It contains more than 50.0 w/v% and not more than 55.0 w/v% of benzalkonium chloride (C <sub>22</sub> H <sub>40</sub> ClN: 354.01).
346 right	↓ 24	When 0.1 µL of the standard solution (1) is injected, adjust the sensitivity of the detector so that the peak height of ethylbenzene is <u>not less than 30%</u> of the full scale of the recorder.	When 0.1 µL of the standard solution (1) is injected, adjust the sensitivity of the detector so that the peak height of ethylbenzene is <u>not more than 30%</u> of the full scale of the recorder.
346 right	↑ 3	When 0.1 µL of the standard solution (2) is injected, adjust the sensitivity of the detector so that the peak height of ethylbenzene is <u>not less than 30%</u> of the full scale of the recorder.	When 0.1 µL of the standard solution (2) is injected, adjust the sensitivity of the detector so that the peak height of ethylbenzene is <u>not more than 30%</u> of the full scale of the recorder.
356 right	↑ 18	Pipet 5 mL of this solution, add exactly 20 mL of the internal standard solution <u>and 5 mL of water</u> , and use this solution as the standard solution.	Pipet 5 mL of this solution, add exactly 20 mL of the internal standard solution, and use this solution as the standard solution.
390 left	↓ 15	Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS = <u>5.005 mg</u> of CaCO <sub>3</sub>	Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS = <u>5.004 mg</u> of CaCO <sub>3</sub>
403 right	↓ 5	(2S)-1-[(2S)-2-Methyl-3-sulfanylpropanoyl]pyrrolidine-2-carboxylic acid	(2S)-1-[(2S)-2-Methyl-3-sulfanylpropanoyl]pyrrolidine-2-carboxylic acid
405 left	↓ 16	[51460-26-5, anhydride]	[52422-26-5, anhydride]
417 left	↓ 28	<u>System performance: When the procedure is run with 20 µL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of cefaclor are not less than 40,000 steps and 0.8 to 1.3, respectively.</u> <u>System repeatability: When the test is repeated 3 times with 20 µL of the standard solution under the above operating conditions, the relative standard deviations of the peak areas of cefaclor are not more than 2.0%.</u>	<u>System performance, and system repeatability: Proceed as directed in the system suitability in the Purity (3) under Cefaclor.</u>
420 right	↑ 24	Amount [mg (potency)] of cefaclor (C <sub>15</sub> H <sub>14</sub> ClN <sub>3</sub> O <sub>4</sub> S) = $W_S \times (Q_T/Q_S) \times 1/5$	Amount [mg (potency)] of cefaclor (C <sub>15</sub> H <sub>14</sub> ClN <sub>3</sub> O <sub>4</sub> S) = $W_S \times (Q_T/Q_S) \times 2$
420 right	↑ 1	Amount [mg (potency)] of cefaclor (C <sub>15</sub> H <sub>14</sub> ClN <sub>3</sub> O <sub>4</sub> S) = $W_S \times (Q_T/Q_S) \times 1/5$	Amount [mg (potency)] of cefaclor (C <sub>15</sub> H <sub>14</sub> ClN <sub>3</sub> O <sub>4</sub> S) = $W_S \times (Q_T/Q_S) \times 2$
438 right	↑ 2	<u>Conduct this procedure without exposure to daylight, using light-resistant vessels.</u> To 1 tablet of Cefditoren Pivoxil Tablets	To 1 tablet of Cefditoren Pivoxil Tablets
445 left	↑ 25	and very slightly soluble in tetrahydrofuran. <u>It is hygroscopic.</u>	and very slightly soluble in tetrahydrofuran.
456 right	↑ 2	<u>Plastic containers for aqueous injections may be used.</u>	<u>Polyethylene or polypropylene containers for aqueous injections may be used.</u>



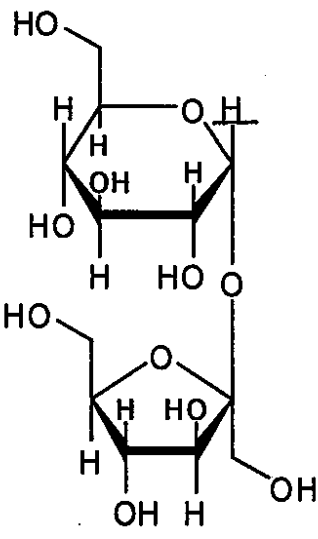
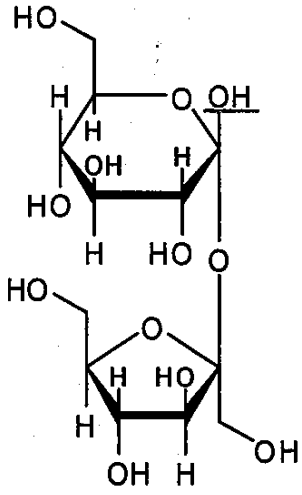


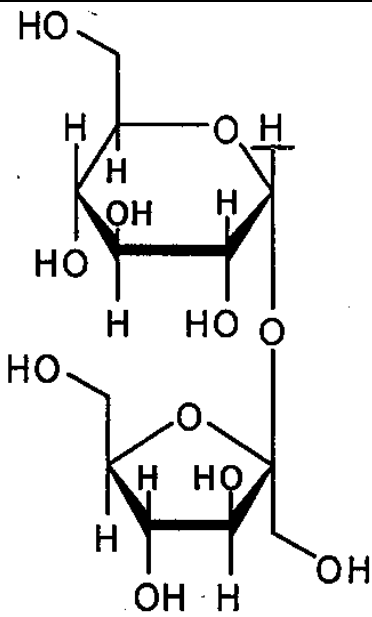
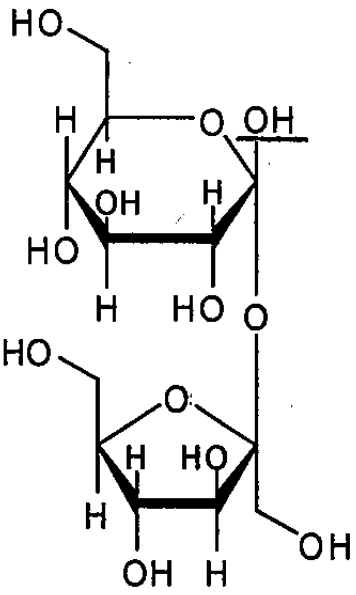
458	right	↑ 23	Plastic containers for aqueous injections may be used.	Polyethylene or polypropylene containers for aqueous injections may be used.
533	left	↑ 14	Dissolve 1.0 g of Cloxacillin Sodium Hydrate in 10 mL of water: the pH of the solution is between <u>5.0</u> and 7.5.	Dissolve 1.0 g of Cloxacillin Sodium Hydrate in 10 mL of water: the pH of the solution is between <u>5.5</u> and 7.5.
547	left	↓ 9	The total amount of sodium chloride and sodium glycolate is not more than 0.5%, <u>calculated on the dried basis</u> .	The total amount of sodium chloride and sodium glycolate is not more than 0.5%.
547	right	↓ 1	W: Amount (g) of sample <u>calculated on the dried basis</u>	W: Amount (g) of sample
547	right	↓ 15	W <sub>1</sub> : Amount (g) of sample <u>calculated on the dried basis</u>	W <sub>1</sub> : Amount (g) of sample
564	right	↑ 12	Each mL of 0.02 mol/L barium chloride VS = <u>0.6414</u> mg of S	Each mL of 0.02 mol/L barium chloride VS = <u>0.6413</u> mg of S
565	right	↓ 13	Each mL of 0.02 mol/L barium chloride VS = <u>0.6414</u> mg of S	Each mL of 0.02 mol/L barium chloride VS = <u>0.6413</u> mg of S
590	right	↓ 4	Each mL of 0.05 mol/L iodine VS = <u>6.212</u> mg of C <sub>3</sub> H <sub>8</sub> OS <sub>2</sub>	Each mL of 0.05 mol/L iodine VS = <u>6.211</u> mg of C <sub>3</sub> H <sub>8</sub> OS <sub>2</sub>
590	right	↑ 4	Each mL of 0.05 mol/L iodine VS = <u>6.212</u> mg of C <sub>3</sub> H <sub>8</sub> OS <sub>2</sub>	Each mL of 0.05 mol/L iodine VS = <u>6.211</u> mg of C <sub>3</sub> H <sub>8</sub> OS <sub>2</sub>
604	left	↑ 11	$[\alpha]_{365}^{20} + 160 - + 174^\circ$	$[\alpha]_{D}^{20} + 160 - + 174^\circ$
605	left	↑ 15	Dissolution rate (%) with respect to the labeled amount of doxifluridine (C <sub>9</sub> H <sub>11</sub> FN <sub>2</sub> O <sub>5</sub> ) = $W_S \times (A_T/A_S) \times (V/V') \times (1/C) \times 45$	Dissolution rate (%) with respect to the labeled amount of doxifluridine (C <sub>9</sub> H <sub>11</sub> FN <sub>2</sub> O <sub>5</sub> ) = $W_S \times (A_T/A_S) \times (V/V') \times (1/C) \times 2$
618	right	↑ 4	Each mL of 0.1 mol/L perchloric acid VS = <u>29.59</u> mg of C <sub>17</sub> H <sub>25</sub> NO.HCl	Each mL of 0.1 mol/L perchloric acid VS = <u>29.58</u> mg of C <sub>17</sub> H <sub>25</sub> NO.HCl
649	left	↑ 20		
649	left	↑ 18	Disodium dihydrogen <u>1-hydroxyethane-1,1-diylidiphosphonate</u>	Disodium dihydrogen <u>(1-hydroxyethylidene)diphosphonate</u>
660	left	↓ 24	To 1 tablet of Faropenem Sodium Tablets add <u>130 mL</u> of water, shake vigorously until the tablets are disintegrated,	To 1 tablet of Faropenem Sodium Tablets add <u>180 mL</u> of water, shake vigorously until the tablets are disintegrated,
666	right	↑ 2	Plastic containers for aqueous injections may be used.	Polyethylene or polypropylene containers for <u>aqueous injection</u> may be used.
671	left	↑ 28	A stainless steel column 4.6 mm in inside diameter and <u>15 cm</u> in length, packed with silica gel (5 mm in particle diameter).	A stainless steel column 4.6 mm in inside diameter and <u>25 cm</u> in length, packed with silica gel (5 mm in particle diameter).
688	left	↓ 2	Plastic containers for aqueous injections may be used.	Polyethylene or polypropylene containers for <u>aqueous injections</u> may be used.
706	left	↑ 13	Dissolve 50 mg of Gonadorelin Acetate in <u>100mL of the mobile phase</u> , and use this solution as the sample solution.	Dissolve 50 mg of Gonadorelin Acetate in <u>100mL of the mobile phase A</u> , and use this solution as the sample solution.
710	left	↓ 18	$F' = (Y_1 - Y_2 - Y_3 + Y_4)^2 / (4fs^2)$	$F' = (Y_1 - Y_2 - Y_3 - Y_4)^2 / (4fs^2)$

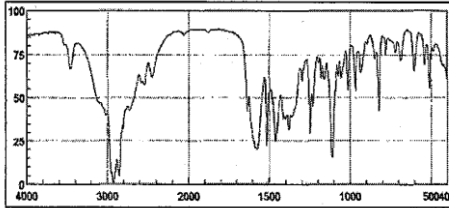
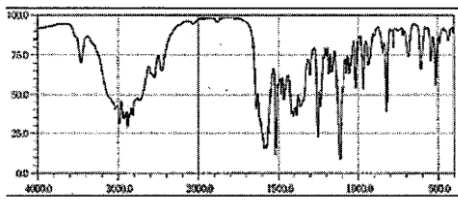
717 right	↓ 27	Time span of measurement: About <u>3 times</u> as long as the retention time of haloperidol beginning after the solvent peak.	Time span of measurement: About <u>2 times</u> as long as the retention time of haloperidol beginning after the solvent peak.
731 right	↑ 5	Content (%) of free phosphoric acid (H <sub>3</sub> PO <sub>4</sub> ) = (A <sub>T</sub> /A <sub>S</sub> ) × (1/W) × <u>258.0</u>	Content (%) of free phosphoric acid (H <sub>3</sub> PO <sub>4</sub> ) = (A <sub>T</sub> /A <sub>S</sub> ) × (1/W) × <u>257.8</u>
749 left	↓ 8	Determine the absorption spectrum of a solution of Ifenprodil Tartrate in methanol (1 in <u>10,000</u> ) as directed under Ultraviolet-visible Spectrophotometry <2.24>, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.	Determine the absorption spectrum of a solution of Ifenprodil Tartrate in methanol (1 in <u>100,000</u> ) as directed under Ultraviolet-visible Spectrophotometry <2.24>, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.
751 right	↑ 6	Containers— <u>Hermetic containers. Plastic containers for aqueous injections</u> may be used.	Containers— <u>Hermetic containers.</u>
789 right	↓ 18	4) Ammonium <u>&lt;1.02&gt;</u> —Take 0.25 g of Kainic Acid Hydrate,	4) Ammonium—Take 0.25 g of Kainic Acid Hydrate,
791 left	↑ 28	$R = (A/0.0383) \times \{1/(\underline{a \times b})\}$	$R = (A/0.0383) \times \{1/(\underline{a - b})\}$
798 right	↑ 19	Mobile phase: To a volume of a solution of ammonium acetate (77 in <u>5,000</u> ) add diluted phosphoric acid (1 in 150)	Mobile phase: To a volume of a solution of ammonium acetate (77 in <u>500</u> ) add diluted phosphoric acid (1 in 150)
801 left	↑ 11	Mobile phase: To a suitable amount of a solution of ammonium acetate (77 in <u>5,000</u> ) add diluted phosphoric acid (1 in 150)	Mobile phase: To a suitable amount of a solution of ammonium acetate (77 in <u>500</u> ) add diluted phosphoric acid (1 in 150)
882 left	↑ 17	Each mL of 0.5 mol/L potassium hydroxide-ethanol VS = <u>76.08 mg</u> of C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>	Each mL of 0.5 mol/L potassium hydroxide-ethanol VS = <u>76.07 mg</u> of C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>
884 left	↑ 17	Dissolve <u>50 mg</u> of Meticrane in 50 mL of acetonitrile.	Dissolve <u>0.05 g</u> of Meticrane in 50 mL of acetonitrile.
890 left	↓ 5	<u>To a quantity of powdered Metronidazole Tablets, equivalent to 0.1 g of Metronidazole according to the labeled amount, add 100 mL of 0.1 mol/L hydrochloric acid TS, stand for 30 minute while occasional shaking. After shaking vigorously, centrifuge, and to 1 mL of the supernatant liquid add 0.1 mol/L hydrochloric acid TS to make exactly 100 mL. Determine the absorption spectrum of this solution</u>	<u>Determine the absorption spectrum of the sample solution obtained in the Assay</u>
895 right	↓ 5	(3R,4S,5S,6R,8R,9R,10E,12E,15R)-9-Acetoxy-5-[3-O-acetyl-2,6-dideoxy-3-C-methyl-4-O-propanoyl- $\alpha$ -L-ribo-hexopyranosyl-(1→4)-3,6-dideoxy-3-dimethylamino- $\beta$ -D-glucopyranosyloxy]-6-formylmethyl-4-methoxy-8-methyl-3-	(3R,4S,5S,6R,8R,9R,10E,12E,15R)-9-Acetoxy-5-[3-O-acetyl-2,6-dideoxy-3-C-methyl-4-O-propanoyl- $\alpha$ -L-ribo-hexopyranosyl-(1→4)-3,6-dideoxy-3-dimethylamino- $\beta$ -D-glucopyranosyloxy]-6-formylmethyl-4-methoxy-8-methyl-3-propanoyloxyhexadeca-10,12-dien-15-olide

		propioyloxyhexadeca-10,12-dien-15-olide	
900 right	↑ 17	It is <u>gradually colored to yellow-brown</u> by light.	It is <u>colored</u> by light.
901 left	↓ 9	Dissolve <u>0.40 g</u> of Morphine Hydrochloride Hydrate in 10 mL of water: the solution is <u>clear</u> , and its absorbance at 420 nm <u>determined as directed under Ultraviolet-visible Spectrophotometry &lt;2.24&gt; is not more than 0.12.</u>	Dissolve <u>0.10 g</u> of Morphine Hydrochloride Hydrate in 10 mL of water: the solution is <u>clear and colorless.</u>
901 right	↓ 2	Morphine Hydrochloride Injection is a <u>colorless or pale yellow-brown</u> , clear liquid. It is <u>gradually colored to yellow-brown</u> by light.	Morphine Hydrochloride Injection is a clear, <u>colorless</u> liquid. It is <u>affected</u> by light.
920 left	↑ 8	Internal standard solution—A solution of nicotinic acid (1 in <u>25,000</u> ).	Internal standard solution—A solution of nicotinic acid (1 in <u>1250</u> ).
920 right	↓ 12	<u>the internal standard</u> and nicotinamide are eluted in this order	<u>nicotinic acid</u> and nicotinamide are eluted in this order
942 left	↑ 3	<u>Separately, weigh accurately about 25 mg of morphine hydrochloride for assay, dissolve in 10 mL of the internal standard solution and add water to make exactly 50 mL, and use this solution as the standard solution. Perform the test with 20 μL each of the sample solution and standard solution as directed under Liquid Chromatography &lt;2.01&gt; according to the following conditions, and calculate the ratios, <math>Q_T</math> and <math>Q_S</math>, of the peak area of morphine to that of the internal standard.</u>	<u>Proceed as directed in the Assay (1) under Opium Alkaloids Hydrochlorides.</u>

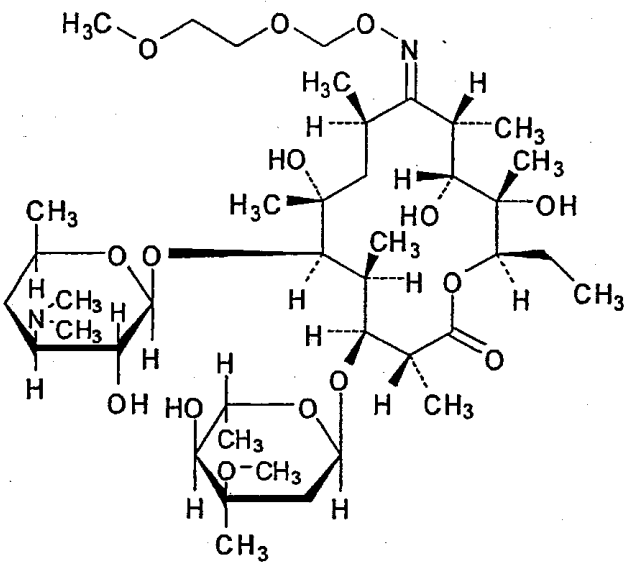
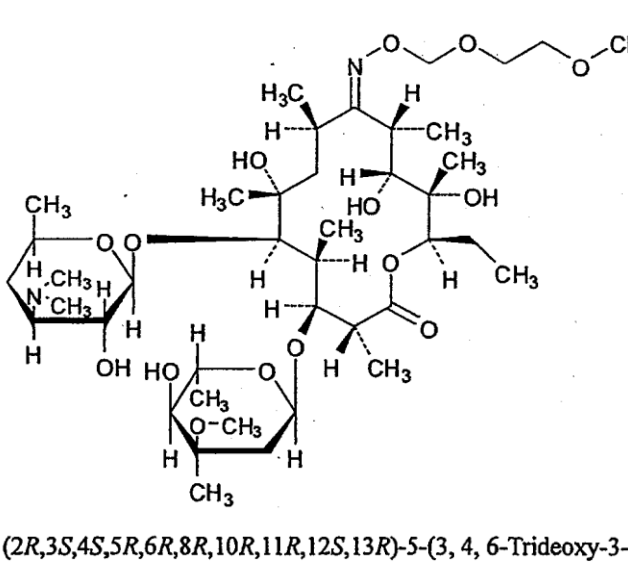
942 right	↓ 4	<p><i>Internal standard solution</i> — A solution of etilefrine hydrochloride (1 in 500).</p> <p><u><i>Operating conditions</i></u> —</p> <p><u>Detector: An ultraviolet absorption photometer (wavelength: 285 nm).</u></p> <p><u>Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecyl- silanized silica gel for liquid chromatography (5 µm in particle diameter).</u></p> <p><u>Column temperature: A constant temperature of about 40°C.</u></p> <p><u>Mobile phase: Dissolve 1.0 g of sodium lauryl sulfate in 500 mL of diluted phosphoric acid (1 in 1000), and adjust the pH to 3.0 with sodium hydroxide TS. To 240 mL of this solution add 70 mL of tetrahydrofuran, and mix.</u></p> <p><u>Flow rate: Adjust the flow rate so that the retention time of morphine is about 10 minutes.</u></p> <p><u><i>System suitability</i></u> —</p> <p><u>System performance: When the procedure is run with 20 µL of the standard solution under the above operating conditions, morphine and the internal standard are eluted in this order with the resolution between these peaks being not less than 3.</u></p> <p><u>System repeatability: When the test is repeated 6 times with 20 µL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of morphine to that of the internal standard is not more than 1.0%.</u></p>	<p><i>Internal standard solution</i> — A solution of etilefrine hydrochloride (1 in 500).</p>
969 right	↓ 9	The mass-average molecular mass ranges between 4500 and <u>6500</u> .	The mass-average molecular mass ranges between 4500 and <u>6400</u> .
969 right	↑ 5	The mass-average molecular mass ranges between 4500 and <u>6500</u> .	The mass-average molecular mass ranges between 4500 and <u>6400</u> .
970 right	↓ 1	$= \frac{\sum(n_i \cdot M_i)}{\sum n_i}$	$= \frac{\sum(n_i \cdot M_i)}{\sum n_j}$
970 right	↓ 4	$M_i$ : Molecular mass of fraction i in main peak	$M_i$ : Molecular mass of fraction i in main peak $\sum n_j$ : Sum of differential refractometer strength in the each fraction between 1500 and 10,000 molecular mass in the main peak
994 left	↓ 20	<u>Light-resistant, at a cold place, or replacing the air with Nitrogen.</u>	<u>Light-resistant, at a cold place.</u>
996 right	↓ 14	It is freely soluble in acetic acid (100), <u>practically insoluble in ethanol (99.5), and very slightly soluble in water.</u>	It is freely soluble in acetic acid (100), <u>very slightly soluble in water and in ethanol (99.5).</u>
999 left	↓ 22	<u>Plastic containers for aqueous injections may be used.</u>	<u>Polyethylene or polypropylene containers for aqueous injections may be used.</u>

1009 right	↓ 28	Each mL of 0.5 mol/L sulfuric acid VS = <u>69.11 mg</u> of K <sub>2</sub> CO <sub>3</sub>	Each mL of 0.5 mol/L sulfuric acid VS = <u>69.10 mg</u> of K <sub>2</sub> CO <sub>3</sub>
1029 left	↑ 19	to 50 mL, <u>and add 10 mL of a solution of potassium bromide (3 in 10)</u> , cool to 15°C,	to 50 mL, cool to 15°C,
1062 left	↑ 13	Content (%) of free phosphoric acid (H <sub>3</sub> PO <sub>4</sub> ) = (A <sub>T</sub> /A <sub>S</sub> ) × (1/W) × <u>258.0</u>	Content (%) of free phosphoric acid (H <sub>3</sub> PO <sub>4</sub> ) = (A <sub>T</sub> /A <sub>S</sub> ) × (1/W) × <u>257.8</u>
1070 left	↑ 8	Test for required detectability: To exactly 1 mL of the <u>standard</u> solution add acetonitrile to make exactly 10 mL.	Test for required detectability: To exactly 1 mL of the <u>sample</u> solution add acetonitrile to make exactly 10 mL.
1072 left	↑ 1	Column: A stainless steel column <u>4.0 mm</u> in inside diameter	Column: A stainless steel column <u>4.6 mm</u> in inside diameter
1073 left	↓ 13	attachment	attachment
1084 right	↑ 19	One serrapeptase Unit corresponds to the amount of serrapeptase which produces <u>1 μg</u> of tyrosine per minute from 5 mL of the substrate solution under the above conditions.	One serrapeptase Unit corresponds to the amount of serrapeptase which produces <u>5 μg</u> of tyrosine per minute from 5 mL of the substrate solution under the above conditions.
1097 left	↓ 11	Each mL of 0.5 mol/L sulfuric acid VS = <u>53.00 mg</u> of Na <sub>2</sub> CO <sub>3</sub>	Each mL of 0.5 mol/L sulfuric acid VS = <u>52.99 mg</u> of Na <sub>2</sub> CO <sub>3</sub>
1114 right	↑ 17	<del>Spiramycin II Acetate</del> (Spiramycin I Acetate): R = 	<del>Spiramycin II Acetate</del> (Spiramycin I Acetate): R = 
1120 left	↓ 11		
1120 left	↑ 24	Separately, to 10 mg each of glucose, <u>lactose monohydrate</u> , fructose and white soft sugar	Separately, to 10 mg each of glucose, <u>lactose hydrate</u> , fructose and white soft sugar

1121 right	↓ 20		
1140 right	↓ 28	to make exactly <u>50 mL</u> , and use this solution as the standard solution.	to make exactly <u>100 mL</u> , and use this solution as the standard solution.
1140 right	↑ 29	is not larger than <u>a half of the peak area</u> of tamsulosin from the standard solution.	is not larger than <u>the peak area</u> of tamsulosin from the standard solution.
1141 left	↓ 15	is not larger than <u>a half of the peak area</u> of tamsulosin from the standard solution.	is not larger than <u>the peak area</u> of tamsulosin from the standard solution.
1142 left	↑ 27	Each mL of 1 mol/L sodium hydroxide VS = <u>75.05 mg</u> of C <sub>4</sub> H <sub>6</sub> O <sub>6</sub>	Each mL of 1 mol/L sodium hydroxide VS = <u>75.04 mg</u> of C <sub>4</sub> H <sub>6</sub> O <sub>6</sub>
1146 left	↓ 10	Measure the absorbances A <sub>T2</sub> and A <sub>S2</sub> at <u>450 nm</u>	Perform the test with these solutions as directed under <u>Ultraviolet-visible spectrophotometry &lt;2.24&gt;</u> , and measure the absorbances A <sub>T2</sub> and A <sub>S2</sub> at <u>450 nm</u>
1159 right	↓ 26	then <u>add 5 mL</u> of a solution prepared by <u>dissolving 0.1 g of 2,3-diaminonaphthalene and 0.5 g of hydroxyammonium chloride in 100 mL of 0.1 mol/L hydrochloric acid TS</u> , shake, and allow to stand for 100 minutes.	then <u>add 5 mL</u> of <u>2,3-diaminonaphthalene TS</u> , shake, and allow to stand for 100 minutes.
1171 left	↓ 17	Each mL of 0.05 mol/L bromine VS = <u>3.756 mg</u> of C <sub>10</sub> H <sub>14</sub> O	Each mL of 0.05 mol/L bromine VS = <u>3.755 mg</u> of C <sub>10</sub> H <sub>14</sub> O
1203 left	↑ 6	Content (%) of the free phosphoric acid (H <sub>3</sub> PO <sub>4</sub> ) = (A <sub>T</sub> /A <sub>S</sub> ) × (1/W) × <u>258.0</u>	Content (%) of the free phosphoric acid (H <sub>3</sub> PO <sub>4</sub> ) = (A <sub>T</sub> /A <sub>S</sub> ) × (1/W) × <u>287.8</u>
1207 right	↑ 24	To 1 tablet of Trimetazidine Hydrochloride Tablets add 15 mL of a mixture of 0.1 mol/L hydrochloric acid TS and ethanol (99.5) (1:1) <u>to disintegrate the tablet, and treat with ultrasonic waves for 10 minutes.</u>	To 1 tablet of Trimetazidine Hydrochloride Tablets add 15 mL of a mixture of 0.1 mol/L hydrochloric acid TS and ethanol (99.5) (1:1), <u>and treat with ultrasonic waves for 10 minutes.</u>
1226 right	↓ 2	so that each mL contains about <u>40 µg</u> of verapamil hydrochloride (C <sub>27</sub> H <sub>38</sub> N <sub>2</sub> O <sub>4</sub> .HCl),	so that each mL contains about <u>40 mg</u> of verapamil hydrochloride (C <sub>27</sub> H <sub>38</sub> N <sub>2</sub> O <sub>4</sub> .HCl),

1236 left	↓ 22	<u>Apply the test to Water for Injection preserved in containers as sterilized products:</u> it meets the requirement.	It meets the requirement.
1259 left	↓ 18	<u>the root with rhizome</u>	<u>the rhizome and root</u>
1272 left	↑ 12	Cimicifuga Rhizome is the rhizome of <i>Cimicifuga simplex</i> Wormskjold, <i>Cimicifuga dahurica</i> (Turcz.) <u>Maximowicz</u> , <i>Cimicifuga foetida</i> Linné or <i>Cimicifuga heracleifolia</i> Komarov ( <i>Ranunculaceae</i> ).	Cimicifuga Rhizome is the rhizome of <i>Cimicifuga simplex</i> Wormskjold, <i>Cimicifuga dahurica</i> (Turcz.) <u>Maximmowicz</u> , <i>Cimicifuga foetida</i> Linné or <i>Cimicifuga heracleifolia</i> Komarov ( <i>Ranunculaceae</i> ).
1274 left	↓ 10	Clematis Root is the root and rhizome of <i>Clematis chinensis</i> Osbeck, <i>Clematis mandshurica</i> Ruprecht, or <i>Clematis hexapetala</i> Pallas ( <i>Ranunculaceae</i> ).	Clematis Root is the root and rhizome of <i>Clematis chinensis</i> Osbeck, <i>Clematis manshurica</i> Ruprecht, or <i>Clematis hexapetala</i> Pallas ( <i>Ranunculaceae</i> ).
1367 right	↑ 21	<u>Turmeric</u>	<u>Termeric</u>
1466	bottom		
1679 left	↓ 5	<u>capillary zone electrophoresis</u>	<u>free solution capillary electrophoresis</u>
1700	↓ 1	<u>Nov. 2005 (Rev. 1)</u>	<u>July, 2000</u>
1700	↓ 5	<u>(delete)</u>	Identification Identification
1700	↓ 15	<u>Nov. 2005 (Rev. 1)</u>	<u>Nov. 2003</u>

attachment

<p>correction</p>	 <p>(2R,3S,4S,5R,6R,8R,9E,10R,11R,12S,13R)-5-(3,4,6-Trideoxy-3-dimethylamino-β-D-xylohexopyranosyloxy)-3-(2,6-dideoxy-3-C-methyl-3-O-methyl-α-L-ribohexopyranosyloxy)-6,11,12-trihydroxy-9-(2-methoxyethoxy)methoxyimino-2,4,6,8,10,12-hexamethylpentadecan-13-olide</p>
<p>error</p>	 <p>(2R,3S,4S,5R,6R,8R,10R,11R,12S,13R)-5-(3,4,6-Trideoxy-3-dimethylamino-β-D-xylohexopyranosyloxy)-3-(2,6-dideoxy-3-C-methyl-3-O-methyl-α-L-ribohexopyranosyloxy)-6,11,12-trihydroxy-9-(2-methoxyethoxy)methoxyimino-2,4,6,8,10,12-hexamethylpentadecan-13-olide</p>