JP18 table of errata

June 3, 2022

Official Monographs

Dextran 40　デキストラン 40

Page	Line	Correction	Error
p838	left↑26	**(6)** Reducing substances—Weigh exactly 3.00 g of Dextran 40, previously dried, dissolve in water to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh exactly 0.450 g of glucose, previously dried, dissolve in water to make exactly 500 mL, and use this solution as the control solution. Pipet 5 mL each of the sample solution and the control solution, and add water to make exactly 50 mL, respectively. Pipet 5 mL each of these solutions, add 5 mL of alkali copper TS, exactly measured, and heat for 15 minutes in a water bath.	**(6)** Reducing substances—Weigh exactly 3.00 g of Dextran 40, previously dried, dissolve in water to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh exactly 0.450 g of glucose, previously dried, dissolve in water to make exactly 500 mL, and use this solution as the control solution. Pipet 5 mL each of the sample solution and the control solution, and add water to make exactly 50 mL, respectively. Pipet 5 mL each of these solutions, add 5 mL of alkaline copper TS, exactly measured, and heat for 15 minutes in a water bath.

Dextran 70　デキストラン 70

Page	Line	Correction	Error
p839	left↑1	**(6)** Reducing substances—Weigh exactly 3.00 g of Dextran 70, previously dried, dissolve in water to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh exactly 0.300 g of glucose, previously dried, dissolve in water to make exactly 500 mL, and use this solution as the control solution. Pipet 5 mL each of the sample solution and the control solution, and add water to make exactly 50 mL, respectively. Pipet 5 mL of these diluted solutions, add exactly 5 mL of alkali copper TS, and heat for 15 minutes in a water bath.	**(6)** Reducing substances—Weigh exactly 3.00 g of Dextran 70, previously dried, dissolve in water to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh exactly 0.300 g of glucose, previously dried, dissolve in water to make exactly 500 mL, and use this solution as the control solution. Pipet 5 mL each of the sample solution and the control solution, and add water to make exactly 50 mL, respectively. Pipet 5 mL of these diluted solutions, add exactly 5 mL of alkaline copper TS, and heat for 15 minutes in a water bath.

Crude Drugs and Related Drugs

Curcuma Rhizome　ガジュツ

Page	Line	Correction	Error
p1994	left↓25-26	**Identification** To 2.0 g of pulverized Curcuma Rhizome add 5 mL of water, shake, then add 5 mL of hexane, shake for 10 minutes, centrifuge, and use the hexane layer as the sample solution. Perform the test with this solution as directed under Thin-layer Chromatography <2.03>. Spot 5 mL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (4:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat the plate at 105 ºC for 5 minutes: a deep blue to dark brown spot and a red-brown to brown spot appear at *R*f values of about 0.3 and about 0.2, respectively.	**Identification** To 2.0 g of pulverized Curcuma Rhizome add 5 mL of water, shake, then add 5 mL of hexane, shake for 10 minutes, centrifuge, and use the hexane layer as the sample solution. Perform the test with this solution as directed under Thin-layer Chromatography <2.03>. Spot 5 mL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (4:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybezaldehyde-sulfuric acid TS on the plate, and heat the plate at 105 ºC for 5 minutes: a deep blue to dark brown spot and a red-brown to brown spot appear at *R*f values of about 0.3 and about 0.2, respectively.

Goshajinkigan Extract　牛車腎気丸エキス

Page	Line	Correction	Error
p2019	left↓3-4	**(2)** To 2.0 g of the dry extract (or 6.0 g of the viscous extract), add 10 mL of water, shake,	**(2)** To 2.0 g of the dry extract (or 6.0 g of the viscous extract), add 10 mL of water, shake,

		then add 5 mL of 1- butanol, shake, centrifuge, and use the 1-butanol layer as the sample solution. Separately, dissolve 1 mg of loganin for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with chromatography. Develop the plate with a mixture of ethyl acetate, water and formic acid (6:1:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat the plate at 105 ºC for 2 minutes: one of the several spots obtained from the sample solution has the same color tone and *R*f value with the purple spot from the standard solution (Cornus Fruit).	then add 5 mL of 1- butanol, shake, centrifuge, and use the 1-butanol layer as the sample solution. Separately, dissolve 1 mg of loganin for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with chromatography. Develop the plate with a mixture of ethyl acetate, water and formic acid (6:1:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-methoxybezaldehyde-sulfuric acid TS on the plate, and heat the plate at 105ºC for 2 minutes: one of the several spots obtained from the sample solution has the same color tone and *R*f value with the purple spot from the standard solution (Cornus Fruit).

Hachimijiogan Extract　八味地黄丸エキス

Page	Line	Correction	Error
p2024	right↓19-20	**(2)** To 2.0 g of the dry extract (or 6.0 g of the viscous extract), add 10 mL of water, shake, then add 5 mL of 1-butanol, shake, centrifuge, and use the 1-butanol layer as the sample solution. Separately, dissolve 1 mg of loganin for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography <2.03>. Spot 10 mL of the sample solution and 2 mL of the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water and formic acid (6:1:1) to a distance of about10 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat the plate at 105ºC for 2 minutes: one of the several spots obtained from the sample solution has the same color tone and *R*f value with the purple spot from the standard solution (Cornus Fruit).	**(2)** To 2.0 g of the dry extract (or 6.0 g of the viscous extract), add 10 mL of water, shake, then add 5 mL of 1-butanol, shake, centrifuge, and use the 1-butanol layer as the sample solution. Separately, dissolve 1 mg of loganin for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography <2.03>. Spot 10 mL of the sample solution and 2 mL of the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water and formic acid (6:1:1) to a distance of about10 cm, and air-dry the plate. Spray evenly 4-methoxybezaldehyde-sulfuric acid TS on the plate, and heat the plate at 105ºC for 2 minutes: one of the several spots obtained from the sample solution has the same color tone and *R*f value with the purple spot from the standard solution (Cornus Fruit).

JP18 table of errata　part 2

September 14, 2022

Official Monographs

Bicalutamide　ビカルタミド

Page	Line	Correction	Error
550	left↑21-20	Determine each peak area by the automatic integration method: the peak areas of related substance M, having the relative retention time of about 0.26 to bicalutamide, related substance N, having the relative retention time of about 0.34, related substance K, having the relative retention time of about 1.03 and related substance L, having the relative retention time of about 1.13, obtained from the sample solution, are not larger than the peak area of bicalutamide from the standard solution,	Determine each peak area by the automatic integration method: the peak areas of related substance M, having the relative retention time of about 0.26 to bicalutamide, related substance N, having the relative retention time of about 0.34, related substance L, having the relative retention time of about 1.03 and related substance K, having the relative retention time of about 1.13, obtained from the sample solution, are not larger than the peak area of bicalutamide from the standard solution,

Candesartan Cilexetil and Amlodipine Besylate Tablets　カンデサルタンシレキセチル･アムロジピンベシル酸塩錠

Page	Line	Correction	Error
615-618		Amlodipine Besilate	Amlodipine Besylate

Imidapril Hydrochloride Tablets　イミダプリル塩酸塩錠

Page	Line	Correction	Error
1143	left↑29-28	Add diluted methanol (2 in 5) to make 50 mL,	Add diluted ethanol (2 in 5) to make 50 mL,

Zopiclone　ゾピクロン

Page	Line	Correction	Error
1935	right↓33-36	determine each peak area by the automatic integration method: the peak areas of related substance A, having the relative retention time of about 0.1 to zopiclone, related substance B, having the relative retention time of about 0.2, related substance C, having the relative retention time of about 0.5, related substance D, having the relative retention time of about 0.9, obtained from the sample solution are not larger than 1/10 times the peak area of zopiclone from the standard solution, and the area of the peak other than zopiclone and the peaks mentioned above from the sample solution is not lager than 1/10 times the peak area of zopiclone from the standard solution.	determine each peak area by the automatic integration method: the peak areas of related substance A, having the relative retention time of about 0.1 to zopiclone, related substance B, having the relative retention time of about 0.2, related substance C, having the relative retention time of about 0.5, related substance D, having the relative retention time of about 0.9 and the peaks other than mentioned above, obtained from the sample solution, are not larger than 1/10 times the peak area of zopiclone from the standard solution.

JP18 table of errata　part 3

November 10, 2023

General Tests / 1.09 Qualitative Tests

Page	Line	Correction	Error
34	left ↑6	After cooling, dissolve the residue in diluted dilute hydrochloric acid (1 in 5), and filter if necessary.	After cooling, dissolve the residue in diluted hydrochloric acid (1 in 5), and filter if necessary.

General Tests / 7.03 Test for Rubber Closure for Aqueous Infusions

Page	Line	Correction	Error
202	left ↓17	Further, to exactly 1 mL of Standard Zinc Solution for atomic absorption spectrophotometry add diluted dilute nitric acid (1 in 3) to make exactly 20 mL, and use this solution as the standard solution.	Further, to exactly 1 mL of Standard Zinc Solution for atomic absorption spectrophotometry add diluted nitric acid (1 in 3) to make exactly 20 mL, and use this solution as the standard solution.

General Tests / 9.22 Standard Solutions

Page	Line	Correction	Error
219	left ↑21-23	**Standard Cadmium Solution** Measure exactly 10 mL of Standard Cadmium Stock Solution, and add diluted dilute nitric acid (1 in 3) to make exactly 1000 mL. Pipet 10 mL of this solution, and add diluted dilute nitric acid (1 in 3) to make 100 mL. Each mL of this solution contains 0.001 mg of cadmium (Cd). Prepare before use.	**Standard Cadmium Solution** Measure exactly 10 mL of Standard Cadmium Stock Solution, and add diluted nitric acid (1 in 3) to make exactly 1000 mL. Pipet 10 mL of this solution, and add diluted nitric acid (1 in 3) to make 100 mL. Each mL of this solution contains 0.001 mg of cadmium (Cd). Prepare before use.

Official Monographs

Aminophylline Hydrate　アミノフィリン水和物

Page	Line	Correction	Error
448	right ↓5	$(C_7H_8N_4O_2)_2$・$C_2H_8N_2$・xH_2O	$C_{14}H_{16}N_8O_4$.$C_2H_8N_2$. xH_2O

L-Aspartic Acid　L-アスパラギン酸

Page	Line	Correction	Error
487	right ↑19	(3) Sulfate <*1.14*>—Dissolve 0.6 g of L-Aspartic Acid in 5 mL of dilute hydrochloric acid and 30 mL of water, add water to make 45 mL, and add 5 mL of barium chloride TS. Perform the test with this solution as the test solution. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS, add 5 mL of dilute hydrochloric acid and water to make 45 mL, and add 5 mL of barium chloride TS (not more than 0.028%).	(3) Sulfate <*1.14*>—Dissolve 0.6 g of L-Aspartic Acid in 5 mL of dilute hydrochloric acid and 30 mL of water, add water to make 45 mL, and add 5 mL of barium chloride TS. Perform the test with this solution as the test solution. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS, add 5 mL of dilute hydrochloric acid and water to make 45 mL, and add 5 mL of barium chloride (not more than 0.028%).

Bicalutamide　ビカルタミド

Page	Line	Correction	Error
550	left ↑4	For the areas of the peaks, related substance G, having the relative retention times of about 0.21 and about 0.25, related substance I, having the relative retention time of about 0.23, related substance M, related substance N, related substance O, having the relative retention time of about 0.55, related substance A, having the relative retention time of about 0.95, and related substance K, and related substance P, having the relative retention time of about 1.09 from the sample solution, multiply their correction factors, 0.5, 0.5, 0.5, 0.4, 0.7, 0.5, 1.1, 0.9 and 0.7, respectively.	For the areas of the peaks, related substance G, having the relative retention times of about 0.21 and about 0.25, related substance I, having the relative retention time of about 0.23, related substance M, related substance N, related substance O, having the relative retention time of about 0.55, related substance A, having the relative retention time of about 0.95, and related substance L, and related substance P, having the relative retention time of about 1.09 from the sample solution, multiply their correction factors, 0.5, 0.5, 0.5, 0.4, 0.7, 0.5, 1.1, 0.9 and 0.7, respectively.

Ciprofloxacin Hydrochloride Hydrate　シプロフロキサシン塩酸塩水和物

Page	Line	Correction	Error
765	left ↓8	[*86393-32-0*, monohydrate]	[*86393-32-0*, monohydrochloride monohydrate]

Clotrimazole　クロトリマゾール

Page	Line	Correction	Error
799	right ↑9	(3) Sulfate <*1.14*>—Dissolve 0.5 g of Clotrimazole in 10 mL of methanol, and add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS, 10 mL of methanol, 1 mL of dilute hydrochloric acid and water to make 50 mL (not more than 0.048%).	(3) Sulfate <*1.14*>—Dissolve 0.5 g of Clotrimazole in 10 mL of methanol, and add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.05 mL of 0.005 mol/L sulfuric acid VS, 10 mL of methanol, 1 mL of dilute hydrochloric acid and water to make 50 mL (not more than 0.048%).

Fursultiamine Hydrochloride　フルスルチアミン塩酸塩

Page	Line	Correction	Error
1051	right ↓27	[*2105-43-3*]	[*804-30-8*, Fursultiamine]

Glycerin　グリセリン

Page	Line	Correction	Error
1080	left ↓14	**Description** Glycerin is a clear, colorless, viscous liquid.	**Description** Glycerin is a clear, colorless, viscous liquid. It has a sweet taste.

Dental Iodine Glycerin　歯科用ヨード・グリセリン

Page	Line	Correction	Error
1173	left ↓24	(2) Potassium iodide—Separate the water layers of the sample solution and standard solution obtained in (1), pipet 7mL each of the water layers, and to each add exactly 1mL of diluted dilute hydrochloric acid (1 in 2), 1 mL of sodium nitrite TS and 10 mL of a mixture of chloroform and hexane (2:1), and shake immediately.	(2) Potassium iodide—Separate the water layers of the sample solution and standard solution obtained in (1), pipet 7mL each of the water layers, and to each add exactly 1mL of diluted hydrochloric acid (1 in 2), 1 mL of sodium nitrite TS and 10 mL of a mixture of chloroform and hexane (2:1), and shake immediately.

Ketoprofen　ケトプロフェン

Page	Line	Correction	Error
1224	right ↑ 20,21,23	Control solution: To a mixture of 0.6 mL of Cobalt (II) Chloride CS and 2.4 mL of Iron (III) Chloride CS add diluted dilute hydrochloric acid (1 in 10) to make 10 mL. To 5.0 mL of this solution add diluted dilute hydrochloric acid (1 in 10) to make 100 mL.	Control solution: To a mixure of 0.6 mL of Cobalt (II) Chloride CS and 2.4 mL of Iron (III) Chloride CS add diluted hydrochloric acid (1 in 10) to make 10 mL. To 5.0 mL of this solution add diluted hydrochloric acid (1 in 10) to make 100 mL.

Loxoprofen Sodium Hydrate　ロキソプロフェンナトリウム水和物

Page	Line	Correction	Error
1279	right ↓17	[*226721-96-6*]	[*80382-23-6*]

Miconazole　ミコナゾール

Page	Line	Correction	Error
1357	right ↑12	**Loss on drying** <*2.41*> Not more than 0.5% (1 g, in vacuum,silica gel, 60℃, 3 hours).	**Loss on drying** <*2.41*> Not more than 0.5% (1 g, in vacuum,silica gel, 60%, 3 hours).

Mosapride Citrate Tablets　モサプリドクエン酸塩錠

Page	Line	Correction	Error
1389	right ↓5	Add 9 mL of methanol, shake for 20 minutes, centrifuge, and use the supernatant liquid as the sample solution. Pipet 1 mL of this solution, add methanol to make exactly 20 mL. Pipet 2 mL of this solution, add methanol to make exactly 20 mL, and use this solution as the standard solution.	Add 9 mL of methanol, shake for 20 minutes, centrifuge, and use the supernatant liquid as the sample solution. Pipet 1 mL of this solution, add methanol to make exactly 20 mL. Pipet 2 mL of the sample solution, add methanol to make exactly 20 mL, and use this solution as the standard solution.

Pitavastatin Calcium Hydrate　ピタバスタチンカルシウム水和物

Page	Line	Correction	Error
1540	right ↓5	The control solution is prepared as follows: Take 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 10), and fire the ethanol to burn. Hereafter, proceed as for the test solution, then add 2.0 mL of Standard Lead Solution, 2 mL of dilute acetic acid and water to make 50 mL (not more than 20 ppm).	The control solution is prepared as follows: Take 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 10), and fire the ethanol to burn. Hereafter, proceed as for the test solution, then add 2.0 mL of Standard Lead Solution, 2 mL of acetic acid and water to make 50 mL (not more than 20 ppm).

Pitavastatin Calcium Tablets　ピタバスタチンカルシウム錠

Page	Line	Correction	Error
1545	left ↓1-2	6-{2-[2-Cyclopropyl-4-(4-fluorophenyl)quinolin-3-yl]ethenyl}-4-hydroxyoxane-2-one	6-{2-[2-cyclopropyl-4-(4-fluorophenyl)quinolin-3-yl]ethenyl}-4-hydroxyoxane-2-one

D-Sorbitol　D-ソルビトール

Page	Line	Correction	Error
1733	right ↓ 10-11	(7) Glucose—Dissolve 20.0 g of D-Sorbitol in 25 mL of water, and boil gently with 40 mL of Fehling's TS for 3 minutes. After cooling, filter the supernatant liquid cautiously through a glass filter (G4), leaving the precipitate in the flask as much as possible, wash the precipitate with hot water until the last washings no longer show alkalinity, and filter the washings through the glass filter.	(7) Glucose—Dissolve 20.0 g of D-Sorbitol in 25 mL of water, and boil gently with 40 mL of Fehling's TS for 3 minutes. After cooling, filter the supernatant liquid cautiously through a glass filter (G4), leaving the precipitate in the flask as much as possible, wash the precipitate with hot water until the last washings no longer show an alkali reaction, and filter the washings through the glass filter.

Voglibose　ボグリボース

Page	Line	Correction	Error
1911	left ↑25	It is very soluble in water, freely soluble in acetic acid (100), slightly soluble in methanol, and very slightly soluble in ethanol (99.5).	It is very slightly soluble in water, freely soluble in acetic acid (100), slightly soluble in methanol, and very slightly soluble in ethanol (99.5).

Zopiclone　ゾピクロン

Page	Line	Correction	Error
1935	right↓33-36	determine each peak area by the automatic integration method: the peak areas of related substance A, having the relative retention time of about 0.1 to zopiclone, related substance B, having the relative retention time of about 0.2, related substance C, having the relative retention time of about 0.5, related substance D, having the relative retention time of about 0.9, obtained from the sample solution are not larger than 1/10 times the peak area of zopiclone from the standard solution, and the area of the peak other than zopiclone and the peaks mentioned above from the sample solution is not larger than 1/10 times the peak area of zopiclone from the standard solution.	determine each peak area by the automatic integration method: the peak areas of related substance A, having the relative retention time of about 0.1 to zopiclone, related substance B, having the relative retention time of about 0.2, related substance C, having the relative retention time of about 0.5, related substance D, having the relative retention time of about 0.9 and the peaks other than mentioned above, obtained from the sample solution, are not larger than 1/10 times the peak area of zopiclone from the standard solution.

JP18 table of errata　part 4

November 29, 2024

General Tests / 9.41 Reagents, Test Solutions

Page	Line	Correction	Error
335	left　↑2	**Orcine**　$C_7H_8O_2$	**Orcine**　$C_7H_3O_2$

Official Monographs

Bezafibrate　ベザフィブラート

Page	Line	Correction	Error
548	right　↑21 right　↑18	System performance: Dissolve 20 mg of Bezafibrate and 10 mg of 4-chlorobenzoic acid in 70 mL of methanol, and add diluted 0.5 mol/L ammonium acetate TS (1 in 50) to make 100 mL. When the procedure is run with 5 μL of this solution under the above operating conditions, 4-chlorobenzoic acid and bezafibrate are eluted in this order with the resolution between these peaks being not less than 3.	System performance: Dissolve 20 mg of Bezafibrate and 10 mg of 4-chlorobenzoate in 70 mL of methanol, and add diluted 0.5 mol/L ammonium acetate TS (1 in 50) to make 100 mL. When the procedure is run with 5 μL of this solution under the above operating conditions, 4-chlorobenzoate and bezafibrate are eluted in this order with the resolution between these peaks being not less than 3.

Rebamipide　レバミピド

Page	Line	Correction	Error
1627	left　↑14 left　↑8	System performance: Dissolve 20 mg of 4-chlorobenzoic acid in methanol to make 50 mL. To 5 mL of this solution add 5 mL of the sample solution and a mixture of water, 0.05 mol/L phosphate buffer solution (pH 6.0) and methanol (7:7:6) to make 50 mL. When the procedure is run with 10 μL of this solution under the above operating conditions, rebamipide and 4-chlorobenzoic acid are eluted in this order with the resolution between these peaks being not less than 8.	System performance: Dissolve 20 mg of 4-chlorobenzoate in methanol to make 50 mL. To 5 mL of this solution add 5 mL of the sample solution and a mixture of water, 0.05 mol/L phosphate buffer solution (pH 6.0) and methanol (7:7:6) to make 50 mL. When the procedure is run with 10 μL of this solution under the above operating conditions, rebamipide and 4-chlorobenzoate are eluted in this order with the resolution between these peaks being not less than 8.