#### *Official Monographs* Dextran 40 デキストラン 40

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

**Dextran 70** デキストラン 70

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

### Crude Drugs and Related Drugs Curcuma Rhizome ガジュツ

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

### Goshajinkigan Extract 牛車賢気丸エキス

Page	Line	Correction	Error
p2019	left $\downarrow$ 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,	then add 5 mL of 1- butanol, shake, centrifuge,
and use the 1-butanol layer as the sample	and use the 1-butanol layer as the sample
solution. Separately, dissolve 1 mg of loganin	solution. Separately, dissolve 1 mg of loganin
for thin-layer chromatography in 1 mL of	for thin-layer chromatography in 1 mL of
methanol, and use this solution as the standard	methanol, and use this solution as the standard
solution. Perform the test with	solution. Perform the test with
chromatography. Develop the plate with a	chromatography. Develop the plate with a
mixture of ethyl acetate, water and formic acid	mixture of ethyl acetate, water and formic acid
(6:1:1) to a distance of about 10 cm, and	(6:1:1) to a distance of about 10 cm, and
air-dry the plate. Spray evenly	air-dry the plate. Spray evenly
4-methoxybenzaldehyde-sulfuric acid TS on	4-methoxybezaldehyde-sulfuric acid TS on the
the plate, and heat the plate at 105 °C for 2	plate, and heat the plate at 105°C for 2
minutes: one of the several spots obtained	minutes: one of the several spots obtained
from the sample solution has the same color	from the sample solution has the same color
tone and Rf value with the purple spot from the	tone and <i>R</i> f value with the purple spot from the
standard solution (Cornus Fruit).	standard solution (Cornus Fruit).

#### Hachimijiogan Extract 八味地黄丸エキス

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

#### Official Monographs Bicalutamide ビカルタミド Bio

icalutamide ピカル	ルタミド		
Page	Line	Correction	Error
550 le	eft ↑ 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, <u>related substance K, having the</u> <u>relative retention time of about 1.03</u> and <u>related substance L, having the relative</u> <u>retention time of about 1.13</u> , 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, <u>related substance L, having the</u> <u>relative retention time of about 1.03</u> and <u>related substance K, having the relative</u> <u>retention time of about 1.13</u> , obtained from the sample solution, are not larger than the peak area of bicalutamide from the standard solution,

Candesartan Cilexetil and Amlodipine Besylate Table	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
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Page	Line	Correction	Error
615-618		Amlodipine Bes <u>i</u> late	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 <u>dilute</u> 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
		Further, to exactly 1 mL of Standard Zinc	Further, to exactly 1 mL of Standard Zinc
		Solution for atomic absorption	Solution for atomic absorption
202	left $\downarrow 17$	spectrophotometry add diluted dilute nitric	spectrophotometry add diluted nitric acid (1 in
		acid (1 in 3) to make exactly 20 mL, and use	3) to make exactly 20 mL, and use this
		this solution as the standard solution.	solution as the standard solution.

#### General Tests / 9.22 Standard Solutions

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

#### Official Monographs

Aminophylline Hydrate アミノフィリン水和物

Page	Line	Correction	Error
448	right $\downarrow 5$	$(\underline{C_7H_8N_4O_2})_2 \cdot C_2H_8N_2 \cdot xH_2O$	<u>C14H16N8O4.</u> C2H8N2 <u>.</u> xH2O

## L-Aspartic Acid L-アスパラギン酸

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

#### Bicalutamide ビカルタミド

Page	Line	Correction	Error
		For the areas of the peaks, related substance G,	For the areas of the peaks, related substance G,
		having the relative retention times of about	having the relative retention times of about
		0.21 and about 0.25, related substance I,	0.21 and about 0.25, related substance I,
		having the relative retention time of about	having the relative retention time of about
		0.23, related substance M, related substance N,	0.23, related substance M, related substance N,
		related substance O, having the relative	related substance O, having the relative
550	left $\uparrow 4$	retention time of about 0.55, related substance	retention time of about 0.55, related substance
		A, having the relative retention time of about	A, having the relative retention time of about
		0.95, and related substance K, and related	0.95, and related substance L, and related
		substance P, having the relative retention time	substance P, having the relative retention time
		of about 1.09 from the sample solution,	of about 1.09 from the sample solution,
		multiply their correction factors, 0.5, 0.5, 0.5,	multiply their correction factors, 0.5, 0.5, 0.5,
		0.4, 0.7, 0.5, 1.1, 0.9 and 0.7, respectively.	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
Ē	765	left $\downarrow 8$	[86393-32-0, monohydrate]	[86393-32-0, monohydrochloride monohydrate]

## Clotrimazole クロトリマゾール

Page	Line	Correction	Error
		(3) Sulfate <1.14>—Dissolve 0.5 g of	(3) Sulfate <1.14>—Dissolve 0.5 g of
	right ↑9	Clotrimazole in 10 mL of methanol, and add 1	Clotrimazole in 10 mL of methanol, and add 1
		mL of dilute hydrochloric acid and water to	mL of dilute hydrochloric acid and water to
		make 50 mL. Perform the test using this	make 50 mL. Perform the test using this
799		solution as the test solution. Prepare the	solution as the test solution. Prepare the
		control solution with $0.50$ mL of 0.005 mol/L	control solution with 0.05 mL of 0.005 mol/L
		sulfuric acid VS, 10 mL of methanol, 1 mL of	sulfuric acid VS, 10 mL of methanol, 1 mL of
		dilute hydrochloric acid and water to make 50	dilute hydrochloric acid and water to make 50
		mL (not more than 0.048%).	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 $\downarrow 27$	[ <u>2105-43-3]</u>	[ <u>804-30-8, Fursultiamine]</u>

#### Glycerin グリセリン

Page	Line	Correction	Error
1020	loft 14	<b>Description</b> Glycerin is a clear, colorless,	Description Glycerin is a clear, colorless,
1080	len ↓ 14	viscous liquid.	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
	left ↓24	(2) Potassium iodide—Separate the water	(2) Potassium iodide—Separate the water
		layers of the sample solution and standard	layers of the sample solution and standard
		solution obtained in (1), pipet 7mL each of the	solution obtained in (1), pipet 7mL each of the
1172		water layers, and to each add exactly 1mL of	water layers, and to each add exactly 1mL of
1175		diluted dilute hydrochloric acid (1 in 2), 1 mL	diluted hydrochloric acid (1 in 2), 1 mL of
		of sodium nitrite TS and 10 mL of a mixture of	sodium nitrite TS and 10 mL of a mixture of
		chloroform and hexane (2:1), and shake	chloroform and hexane (2:1), and shake
		immediately.	immediately.

## Ketoprofen f h r r r

Page	Line	Correction	Error
		Control solution: To a mixture of 0.6 mL of	Control solution: To a mixure of 0.6 mL of
		Cobalt (II) Chloride CS and 2.4 mL of Iron	Cobalt (II) Chloride CS and 2.4 mL of Iron
1224	right ↑	(III) Chloride CS add diluted dilute	(III) Chloride CS add diluted hydrochloric acid
1224	20,21,23	hydrochloric acid (1 in 10) to make 10 mL. To	(1 in 10) to make 10 mL. To 5.0 mL of this
		5.0 mL of this solution add diluted dilute	solution add diluted hydrochloric acid (1 in 10)
		hydrochloric acid (1 in 10) to make 100 mL.	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 $\downarrow 17$	[ <u>226721-96-6</u> ]	[ <u>80382-23-6</u> ]

## 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	Loss on drying <2.41> Not more than 0.5% (1
		g, in vacuum,silica gel, 60 <u>°C</u> , 3 hours).	g, in vacuum,silica gel, 60 <u>%</u> , 3 hours).

## Mosapride Citrate Tablets モサプリドクエン酸塩錠

Page	Line	Correction	Error
1389	right $\downarrow 5$	Add 9 mL of methanol, shake for 20 minutes,	Add 9 mL of methanol, shake for 20 minutes,
		centrifuge, and use the supernatant liquid as	centrifuge, and use the supernatant liquid as
		the sample solution. Pipet 1 mL of this	the sample solution. Pipet 1 mL of this
		solution, add methanol to make exactly 20 mL.	solution, add methanol to make exactly 20 mL.
		Pipet 2 mL of this solution, add methanol to	Pipet 2 mL of the sample solution, add
		make exactly 20 mL, and use this solution as	methanol to make exactly 20 mL, and use this
		the standard solution.	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:	The control solution is prepared as follows:
		Take 10 mL of a solution of magnesium nitrate	Take 10 mL of a solution of magnesium nitrate
		hexahydrate in ethanol (95) (1 in 10), and fire	hexahydrate in ethanol (95) (1 in 10), and fire
		the ethanol to burn. Hereafter, proceed as for	the ethanol to burn. Hereafter, proceed as for
		the test solution, then add 2.0 mL of Standard	the test solution, then add 2.0 mL of Standard
		Lead Solution, 2 mL of dilute acetic acid and	Lead Solution, 2 mL of acetic acid and water
		water to make 50 mL (not more than 20 ppm).	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
		6-{2-[2-Cyclopropyl-4-(4-fluorophenyl)quinol	6-{2-[2-cyclopropyl-4-(4-fluorophenyl)quinoli
1545	left $\downarrow 1-2$	in-	n-
		3-yl]ethenyl}-4-hydroxyoxane-2-one	3-yl]ethenyl}-4-hydroxyoxane-2-one

## D-Sorbitol D-ソルビトール

I	Page	Line	Correction	Error
-	Page 1733	Line right ↓ 10-11	Correction (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	Error (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
			through the glass filter.	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 <u>slightly</u> 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.