

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 <u>alkali copper TS</u> , 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 <u>alkaline copper TS</u> , 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 <u>alkali copper TS</u> , 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 <u>alkaline copper TS</u> , 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 <u>4-methoxybenzaldehyde-sulfuric acid TS</u> on the plate, and heat the plate at 105 °C for 5 minutes: a deep blue to dark brown spot and a red-brown to brown spot appear at <i>R_f</i> 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 <u>4-methoxybezaldehyde-sulfuric acid TS</u> on the plate, and heat the plate at 105 °C for 5 minutes: a deep blue to dark brown spot and a red-brown to brown spot appear at <i>R_f</i> 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 <u>4-methoxybenzaldehyde-sulfuric acid TS</u> on the plate, and heat the plate at 105 °C for 2 minutes: one of the several spots obtained from the sample solution has the same color tone and <i>Rf</i> 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 <u>4-methoxybezaldehyde-sulfuric acid TS</u> on the plate, and heat the plate at 105°C for 2 minutes: one of the several spots obtained from the sample solution has the same color tone and <i>Rf</i> value with the purple spot from the standard solution (Cornus Fruit).
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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 <u>4-methoxybenzaldehyde-sulfuric acid TS</u> on the plate, and heat the plate at 105°C for 2 minutes: one of the several spots obtained from the sample solution has the same color tone and <i>Rf</i> 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 <u>4-methoxybezaldehyde-sulfuric acid TS</u> on the plate, and heat the plate at 105°C for 2 minutes: one of the several spots obtained from the sample solution has the same color tone and <i>Rf</i> value with the purple spot from the standard solution (Cornus Fruit).

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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, <u>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,</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 relative retention time of about 1.03 and related substance K, having the relative 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 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 Besylate	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 <u>methanol</u> (2 in 5) to make 50 mL,	Add diluted <u>ethanol</u> (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, <u>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.</u>	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 <u>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.</u>