

事 務 連 絡 令和4年6月3日

各都道府県衛生主管部(局)薬務主管課 御中

厚生労働省医薬・生活衛生局医薬品審査管理課

第十八改正日本薬局方(英文版)正誤表の送付について(その1)

第十八改正日本薬局方(令和3年厚生労働省告示第220号)の英文版につきまして、 一部に誤植等がありましたので別紙のとおり正誤表を送付いたします。

## 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 <u>alkaline copper TS</u> , 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

Dexiral 70 7 TAT 70 70				
Page	Line	Correction	Error	
	left 1	(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		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
Page	Line left 25-26	Correction  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 °C for 5 minutes: a deep blue to dark brown spot and a red-brown to brown spot appear at Rf values of about 0.3 and about 0.2, respectively.	Error  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 °C for 5 minutes: a deep blue to dark brown spot and a red-brown to brown spot appear at Rf values of about 0.3 and about 0.2, respectively.

## Goshajinkigan Extract 牛車賢気丸エキス

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,

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 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-drv the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS 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 Rf 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 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-drv the plate. Spray 4-methoxybezaldehyde-sulfuric acid TS 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 Rf value with the purple spot from the standard solution (Cornus Fruit).

Hachimijiogan Extract 八味地黄丸エキス

Hachimijlogan Extract / 外地與人工十人			
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 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 about 10 cm, and air-dry the plate.	distance of about 10 cm, and air-dry the plate.
		Spray evenly 4-methoxybenzaldehyde-sulfuric	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).