

事 務 連 絡
令和 4 年 6 月 3 日

一般社団法人日本病院薬剤師会 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）

標記について、別添写しのとおり各都道府県衛生主管部（局）薬務主管課宛に連絡しましたので、お知らせいたします。



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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。

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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-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. |

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, |

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| | | 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-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). |
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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 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). | (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 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). |