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加盟団体 殿

日本製薬団体連合会

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 3）

標記について、令和 5 年 11 月 10 日付け事務連絡にて厚生労働省 医薬局 医薬品審査管理課より通知がありました。

つきましては、本件につき貴会会員に周知徹底いただきたく、ご配慮の程よろしくお願い申し上げます。

事 務 連 絡

令和5年 11 月 10 日

日本製薬団体連合会 御中

厚生労働省医薬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3）

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。



事務連絡
令和5年11月10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3）

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。

JP18 table of errata

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
202	left ↓ 17	Further, to exactly 1 mL of Standard Zinc Solution for atomic absorption spectrophotometry add diluted <u>dilute</u> 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 <u>dilute</u> nitric acid (1 in 3) to make exactly 1000 mL. Pipet 10 mL of this solution, and add diluted <u>dilute</u> 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	$(C_7H_8N_4O_2)_2 \cdot C_2H_8N_2 \cdot xH_2O$	$C_{14}H_{16}N_8O_4 \cdot C_2H_8N_2 \cdot xH_2O$

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 <u>TS</u> (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 <u>related substance K</u> , 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 <u>related substance L</u> , 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. <u>It has a sweet taste.</u>

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 <u>mixture</u> 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 <u>mixture</u> 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°C, 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 <u>this</u> 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 <u>the sample</u> 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 <u>dilute acetic acid</u> 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 <u>acetic acid</u> 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 <u>alkalinity</u> , 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 <u>an alkali reaction</u> , 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 <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	<p>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></p>	<p>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></p>