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 dilute 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 dilute 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 dilute nitric acid (1 in 3) to make exactly 1000 mL. Pipet 10 mL of this solution, and add diluted dilute 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	$(C_7H_8N_4O_2)_2$・$C_2H_8N_2$・xH_2O	$C_{14}H_{16}N_8O_4$.$C_2H_8N_2$. 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 TS (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 related substance K, 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 related substance L, 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. It has a sweet taste.

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 mixture 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 mixure 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℃, 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 this 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 the sample 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 dilute acetic acid 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 acetic acid 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 alkalinity, 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 an alkali reaction, 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 slightly 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.