

事 務 連 絡
平成 29 年 11 月 17 日

独立行政法人医薬品医療機器総合機構 御中

厚生労働省医薬・生活衛生局医薬品審査管理課

第十七改正日本薬局方（英文版）正誤表の送付について

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
平成 29 年 11 月 17 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

第十七改正日本薬局方（英文版）正誤表の送付について

第十七改正日本薬局方（平成 28 年厚生労働省告示第 64 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。

Preface

Page	Line	Correction	Error
iii	left ↓ 23	Draft revisions covering subjects in General Notices, General Rules for Crude Drugs, General Rules for Preparations, General Tests and Monographs, for which discussions were finished between October 2013 and July 2015, were prepared for JP 17. They were examined by the Committee on JP in August 2015, followed by the PAFSC in September 2015, and then submitted to the Minister of Health, Labour and Welfare.	Draft revisions covering subjects in General Notices, General Rules for Crude Drugs, General Rules for Preparations, General Tests and Monographs, for which discussions were finished between October 2013 and July 2015, were prepared for <u>a supplement to the JP 17</u> . They were examined by the Committee on JP in August 2015, followed by the PAFSC in September 2015, and then submitted to the Minister of Health, Labour and Welfare.
iii	right ↑ 9	(13) <u>Manufacture</u>	(13) <u>Manufacturing requirement</u>
iv	right ↑ 16	(1) Paragraph 12: The item “ <u>Manufacture</u> ” was newly added in monograph in order to specify the requirements that should be noted on manufacturing processes such as control of intermediates and manufacturing processes.	(1) Paragraph 12: The item “ <u>Manufacturing requirement</u> ” was newly added in monograph in order to specify the requirements that should be noted on manufacturing processes such as control of intermediates and manufacturing processes.
vi	left ↑ 5	Lansoprazole Delayed-release Orally <u>Disintegrating</u> Tablets	Lansoprazole Delayed-release Orally <u>Disintegration</u> Tablets
xiii	right ↑ 25	Satoshi Tanaka	Tomoyuki Tanaka

General Notices

Page	Line	Correction	Error
2	left ↓ 4	<u>Law</u> on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices.	<u>Low</u> on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices.

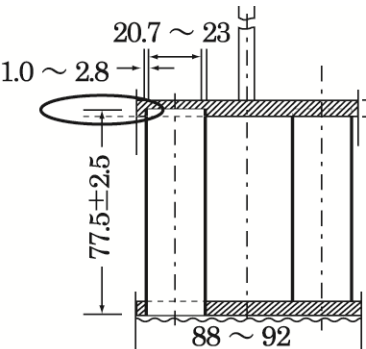
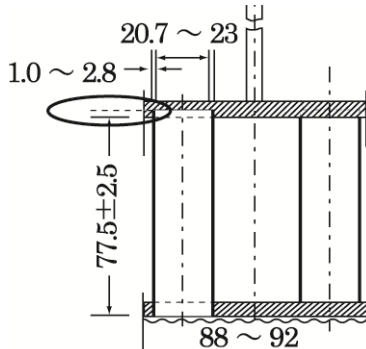
General Tests / 2.57 Boiling Point and Distilling Range Test

Page	Line	Correction	Error
78	Fig. 2.57-1	<p>A: Distilling flask B: Thermometer with an immersion line C: Immersion line D: Cork stopper E: Condenser F: Adapter G: Volumetric cylinder (25 mL, graduated to 0.1 mL)</p> <p>The figures are in mm.</p>	<p>A: Distilling flask B: Thermometer with an immersion line C: Immersion line D: Cork stopper E: Condenser F: Adapter G: Volumetric cylinder (25 mL, graduated to 0.1 mL)</p> <p>The figures are in mm.</p>

General Tests / 5.01 Crude Drugs Test

Page	Line	Correction	Error
136	left ↓ 3	filter paper for <u>quantitative analysis</u>	filter paper for <u>assay</u>
136	left ↓ 16	filter paper for <u>quantitative analysis</u>	filter paper for <u>assay</u>

General Tests / 6.09 Disintegration Test

Page	Line	Correction	Error
155	Fig. 6.09-1 upper left		

General Tests / 9.41 Reagents, Test Solutions

Page	Line	Correction	Error
195	left ↓ 17	Achyranthes root for thin-layer chromatography A heatdried, pulverized root of <i>Achyranthes fauriei</i> H. Léveillé et Vaniot (<i>Amaranthaceae</i>) meeting the following additional specifications.	Achyranthes root for thin-layer chromatography A heatdried, pulverized root of <i>Achyranthes fauriei</i> Leveillé et Vaniot (<i>Amaranthaceae</i>) meeting the following additional specifications.
199	right ↓ 24	Refractive index <2.45> n_D^{20} : 1.450 – 1.455	Refractive index <2.45> n_D^{20} : 1.450 – 1.455
207	left ↑ 3	Artemisia·argyi for purity test Powder of the leaf and twig of <i>Artemisia argyi</i> H. Léveillé et Vaniot (<i>Compositae</i>).	Artemisia·argyi for purity test Powder of the leaf and twig of <i>Artemisia argyi</i> H. Léveillé et Vaniot.
229	right ↓ 5	Digital resolution: 0.25 <u>Hz</u> or lower.	Digital resolution: 0.25 or lower.
259	left ↓ 27	Digital resolution: 0.25 <u>Hz</u> or lower.	Digital resolution: 0.25 or lower.
282	left ↓ 19	Digital resolution: 0.25 <u>Hz</u> or lower.	Digital resolution: 0.25 or lower.
283	left ↓ 10	Digital resolution: 0.25 <u>Hz</u> or lower.	Digital resolution: 0.25 or lower.
286	right ↓ 27	4-Methoxybenzaldehyde-sulfuric acid-acetic acid-ethanol TS for <u>spraying</u>	4-Methoxybenzaldehyde-sulfuric acid-acetic acid-ethanol TS for <u>spray</u>
288	left ↑ 27	Refractive index <2.45> n_D^{20} : 1.420 – 1.425	Refractive index <2.45>: 1.420 – 1.425
299	right ↑ 23	Digital resolution: 0.25 <u>Hz</u> or lower.	Digital resolution: 0.25 or lower.
318	right ↓ 9	Digital resolution: 0.25 <u>Hz</u> or lower.	Digital resolution: 0.25 or lower.
320	left ↑ 22	Digital resolution: 0.25 <u>Hz</u> or lower.	Digital resolution: 0.25 or lower.
322	left ↑ 22	Digital resolution: 0.25 <u>Hz</u> or lower.	Digital resolution: 0.25 or lower.
352	left ↓ 1	zinc iodide-starch TS	zinc iodide-starch <u>paste</u> TS

General Tests / 9.43 Filter Papers, Filters for filtration, Test Papers, Crucibles, etc.

Page	Line	Correction	Error
355	left ↓ 11	filter paper for <u>quantitative</u> analysis	filter paper for <u>volumetric</u> analysis

Official Monographs

Barium Sulfate 硫酸バリウム

Page	Line	Correction	Error
473	right ↓ 16	filter paper for <u>quantitative</u> analysis	filter paper for <u>assay</u>

Anhydrous Dibasic Calcium Phosphate 無水リン酸水素カルシウム

Page	Line	Correction	Error
557	left ↑ 15	filter paper for <u>quantitative</u> analysis	filter paper for <u>assay</u>

Dibasic Calcium Phosphate Hydrate リン酸水素カルシウム水和物

Page	Line	Correction	Error
558	left ↓ 28	filter paper for <u>quantitative analysis</u>	filter paper for <u>assay</u>

Candesartan Cilexetil カンデサルタンシレキセチル

Page	Line	Correction	Error
565	right ↓ 2	the area of the peak other than candesartan cilexetil and the peaks mentioned above from the sample solution is smaller than 1/10 times the peak area of candesartan cilexetil from the standard solution,	the area of the peak other than candesartan cilexetil and the peaks mentioned above from the sample solution is <u>not</u> smaller than 1/10 times the peak area of candesartan cilexetil from the standard solution,

Diflorasone Diacetate ジフロラゾン酢酸エステル

Page	Line	Correction	Error
792	right ↓ 4	6 α ,9-Difluoro-11 β ,17,21-trihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17,21- <u>diacetate</u>	6 α ,9-Difluoro-11 β ,17,21-trihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17,21- <u>diacetate</u>

Docetaxel Injection ドセタキセル注射液

Page	Line	Correction	Error
822	right ↑ 21	It contains not <u>less</u> than 93.0% and not <u>more</u> than 105.0% of the labeled amount of docetaxel (C ₄₃ H ₅₃ NO ₁₄ : 807.88).	It contains not <u>more</u> than 93.0% and not <u>less</u> than 105.0% of the labeled amount of docetaxel (C ₄₃ H ₅₃ NO ₁₄ : 807.88).

Docetaxel for Injection 注射用ドセタキセル

Page	Line	Correction	Error
823	right ↑ 27	It contains not <u>less</u> than 93.0% and not <u>more</u> than 105.0% of the labeled amount of docetaxel (C ₄₃ H ₅₃ NO ₁₄ : 807.88).	It contains not <u>more</u> than 93.0% and not <u>less</u> than 105.0% of the labeled amount of docetaxel (C ₄₃ H ₅₃ NO ₁₄ : 807.88).

Doxifluridine Capsules ドキシフルリジンカプセル

Page	Line	Correction	Error
836	left ↑ 20	$= M_S \times A_T/A_S \times \frac{V}{V'} \times 1/C \times 45$	$= M_S \times A_T/A_S \times \frac{V}{V'} \times 1/C \times 45$

Ebastine エバスタチン

Page	Line	Correction	Error
846	left ↓ 19	with <u>exactly</u> 10 μ L each of the sample solution and standard	with <u>exacty</u> 10 μ L each of the sample solution and standard

Ergometrine Maleate エルゴメトリンマレイン酸塩

Page	Line	Correction	Error
883	left ↓ 4	(8 <u>R</u>)-N-[(1S)-2-Hydroxy-1-methylethyl]-6-methyl-9,10-didehydroergoline-8-carboxamide monomaleate	(8 <u>S</u>)-N-[(1S)-2-Hydroxy-1-methylethyl]-6-methyl-9,10-didehydroergoline-8-carboxamide monomaleate

Guanethidine Sulfate グアネチジン硫酸塩

Page	Line	Correction	Error
1003	right ↑ 2	zinc iodide-starch TS	zinc iodide-starch <u>paste</u> TS

Heparin Calcium ヘパリンカルシウム

Page	Line	Correction	Error
1009	right ↑ 5	It contains not less than 180 Heparin Units (antifactor IIa activity) per mg and not less than 8.0% and not more than 12.0% of calcium (Ca: 40.08), <u>calculated on the dried basis</u> .	It contains not less than 180 Heparin Units (antifactor IIa activity) per mg, <u>calculated on the dried basis</u> , and not less than 8.0% and not more than 12.0% of calcium (Ca: 40.08).

Isomalt Hydrate イソマル水和物

Page	Line	Correction	Error
1098	right ↑ 15	Separately, weigh <u>exactly</u> 10.0 mg of D-sorbitol and 10.0 mg of D-mannitol,	Separately, weigh <u>exactly</u> 10.0 mg of D-sorbitol and 10.0 mg of D-mannitol,

Magnesium Silicate ケイ酸マグネシウム

Page	Line	Correction	Error
1187	right ↑ 2	filter paper for <u>quantitative analysis</u>	filter paper for <u>assay</u>

Methylethergometrine Maleate メチルエルゴメトリンマレイン酸塩

Page	Line	Correction	Error
1233	left ↑ 20	(8 <i>R</i>)- <i>N</i> -[(1 <i>S</i>)-1-(Hydroxymethyl)propyl]-6-methyl-9,10-didehydroergoline-8-carboxamide monomaleate	(8 <i>S</i>)- <i>N</i> -[(1 <i>S</i>)-1-(Hydroxymethyl)propyl]-6-methyl-9,10-didehydroergoline-8-carboxamide monomaleate

Noscapine ノスカピン

Page	Line	Correction	Error
1327	left ↑ 18	Spray evenly dilute bismuth subnitrate-potassium iodide TS for <u>spraying</u> on the plate:	Spray evenly dilute bismuth subnitrate-potassium iodide TS for <u>spray</u> on the plate:

Peplomycin Sulfate ペプロマイシン硫酸塩

Page	Line	Correction	Error
1379	right ↓ 32	in 10mL of diluted nitric acid (1 in 100)	in <u>exactly</u> 10mL of diluted nitric acid (1 in 100)

Pipemidic Acid Hydrate ピペミド酸水和物

Page	Line	Correction	Error
1414	left ↓ 18	It is freely soluble in acetic acid (100), very slightly soluble in water, and practically insoluble in methanol <u>and in ethanol (99.5)</u> .	It is freely soluble in acetic acid (100), very slightly soluble in water <u>and in ethanol (99.5)</u> , and practically insoluble in methanol.

Povidone ポビドン

Page	Line	Correction	Error
1441	left ↓ 19	More than 18 and <u>not</u> more than 95	More than 18 and more than 95

Sevoflurane セボフルラン

Page	Line	Correction	Error
1550	left ↑ 11	Refractive index n_D^{20} : 1.2745 – 1.2760	Refractive index n_{20}^{20} : 1.2745 – 1.2760

Sodium Chloride 塩化ナトリウム

Page	Line	Correction	Error
1569	right ↓ 27	Separately, to 20 mL of the sample solution add 0.1 mL of bromothymol blue- <u>sodium hydroxide-ethanol</u> TS and 0.5 mL of 0.01 mol/L sodium hydroxide VS: the color of the solution is blue.	Separately, to 20 mL of the sample solution add 0.1 mL of bromothymol blue TS and 0.5 mL of 0.01 mol/L sodium hydroxide VS: the color of the solution is blue.
1569	right ↓ 30	To 7.5 mL of the sample solution obtained in (2) add water to make 30 mL, and use this solution as the sample solution.	To 7.5 mL of the sample solution obtained in (2) add water to make <u>exactly</u> 30 mL, and use this solution as the sample solution.

Crude Drugs and Related Drugs

Achyranthes Root ゴシツ

Page	Line	Correction	Error
1792	left ↓ 24	Achyranthes Root is the root of <i>Achyranthes fauriei</i> <u>H. L�veill� et Vaniot</u> or <i>Achyranthes bidentata</i> Blume (<i>Amaranthaceae</i>).	Achyranthes Root is the root of <i>Achyranthes fauriei</i> Leveill� et Vaniot or <i>Achyranthes bidentata</i> Blume (<i>Amaranthaceae</i>).

Mentha Herb ハッカ

Page	Line	Correction	Error
1914	right ↑ 15	Spray evenly 4-methoxybenzaldehyde-sulfuric acid-acetic acid-ethanol TS <u>for spraying</u> on the plate, and heat at 105°C for 5 minutes: one of the spot among the several spots obtained from the sample solution has the same color tone and Rf value with the spot obtained from the standard solution.	Spray evenly 4-methoxybenzaldehyde-sulfuric acid-acetic acid-ethanol TS on the plate, and heat at 105°C for 5 minutes: one of the spot among the several spots obtained from the sample solution has the same color tone and Rf value with the spot obtained from the standard solution.

Peony Root シャクヤク

Page	Line	Correction	Error
1936	left ↓ 12	System repeatability: When the test is repeated 6 times with <u>10 μL</u> of the standard solution under the above operating conditions, the relative standard deviation of the peak area of paeoniflorin is not more than 1.5%.	System repeatability: When the test is repeated 6 times with the standard solution under the above operating conditions, the relative standard deviation of the peak area of paeoniflorin is not more than 1.5%.

Powdered Peony Root シャクヤク末

Page	Line	Correction	Error
1936	right ↑ 6	System repeatability: When the test is repeated 6 times with <u>10 μL</u> of the standard solution under the above operating conditions, the relative standard deviation of the peak area of paeoniflorin is not more than 1.5%.	System repeatability: When the test is repeated 6 times with the standard solution under the above operating conditions, the relative standard deviation of the peak area of paeoniflorin is not more than 1.5%.

Ultraviolet-visible Reference Spectra

Dexamethasone

Page	Line	Correction	Error
2280		<u>240.0</u>	<u>220.0</u>

General Information / Biotechnological/Biological Products

SDS-Polyacrylamide Gel Electrophoresis

Page	Line	Correction	Error
2469	right ↓ 15	(Deleted)	<u>Sodium Dodecyl Sulfate Polyacrylamide Gel Electrophoresis (SDS-PAGE)—Uniform Percentage Gels</u>

General Information / Crude Drugs

Scientific Names used in the JP and Those being used Taxonomically

Page	Line	Correction	Error
2521	↓ 12	<i>Achyranthes fauriei</i> <u>H. Léveillé</u> et Vaniot = <i>Achyranthes fauriei</i> H. Lev. & Vaniot	<i>Achyranthes fauriei</i> <u>Leveille</u> et Vaniot = <i>Achyranthes fauriei</i> H. Lev. & Vaniot

Purity Tests on Crude Drugs using Genetic Information

Page	Line	Correction	Error
2516	right ↓ 17	In particular, it is very easy to classify closely related species using the <u>internal</u> transcriber space (ITS) region of the rDNA region, since by comparison with the coded gene region nucleotide substitution is more often undertaken.	In particular, it is very easy to classify closely related species using the <u>intergenic</u> transcriber space (ITS) region of the rDNA region, since by comparison with the coded gene region nucleotide substitution is more often undertaken.