事 務 連 絡 平成 29 年 11 月 17 日

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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 a supplement to the 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.
iii	right ↑9	(13) Manufacture	(13) Manufacturing requirement
iv	right 16	(1) Paragraph 12: The item "Manufacture" 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 "Manufacturing requirement" 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** 

•	iterat Hottices			
	Page	Line	Correction	Error
		1-0   4	Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and	Low on Securing Quality, Efficacy and Safety
	2	left ↓4	Medical Devices.	Medical Devices.

General Tests / 2.57 Boiling Point and Distilling Range Test

Page	Line	Correction	Error
78	Fig. 2.57-1	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)  The figures are in mm.	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)  The figures are in mm.

General Tests / 5.01 Crude Drugs Test

Page	Line	· Correction	Error
136	left ↓3	filter paper for quantitative analysis	filter paper for assay
136	left ↓16	filter paper for quantitative analysis	filter paper for assay

General Tests / 6.09 Disintegration Test

Page	Line	Correction	Error
155	Fig. 6.09-1 upper left	20.7 ~ 23	20.7 ~ 23 \\ 1.0 ~ 2.8 - \  - \  - \  - \  - \  - \  - \  - \

General Tests / 9.41 Reagents, Test Solutions

ieneral Tests / 9.	.41 Reagents, Tes	t Solutions	
Page	Line	Correction	Error
195	left ↓17	Achyranthes root for thin-layer chromatography A heatdried, pulverized root of Achyranthes fauriei H. Léveillé et Vaniot (Amaranthaceae) meeting the following additional specifications.	Achyranthes root for thin-layer chromatography A heatdried, pulverized root of Achyranthes fauriei Leveillé et Vaniot (Amaranthaceae) meeting the following additional specifications.
199	right ↓ 24	Refractive index $<2.45>n_D^{20}$ : 1.450 – 1.455	Refractive index <2.45> $n_{20}^{20}$ : 1.450 – 1.455
207	left ↑3	Artemisia argyi for purity test Powder of the leaf and twig of Artemisia argyi H. Léveillé et Vaniot (Compositae).	Artemisia argyi for purity test Powder of the leaf and twig of Artemisia argyi H. Léveillé et Vaniot.
229	right ↓5	Digital resolution: 0.25 Hz or lower.	Digital resolution: 0.25 or lower.
259	left ↓27	Digital resolution: 0.25 Hz or lower.	Digital resolution: 0.25 or lower.
282	left ↓ 19	Digital resolution: 0.25 Hz or lower.	Digital resolution: 0.25 or lower.
283	left ↓10	Digital resolution: 0.25 Hz or lower.	Digital resolution: 0.25 or lower.
286	right ↓27	4-Methoxybenzaldehyde-sulfuric acid-acetic acid-ethanol TS for spraying	4-Methoxybenzaldehyde-sulfuric acid-acetic acid-ethanol TS for spray
288	left ↑27	Refractive index <2.45> $n_{\rm D}^{20}$ : 1.420 – 1.425	Refractive index <2.45>: 1.420 – 1.425
299	right ↑23	Digital resolution: 0.25 Hz or lower.	Digital resolution: 0.25 or lower.
318	right ↓9	Digital resolution: 0.25 Hz or lower.	Digital resolution: 0.25 or lower.
320	left ↑22	Digital resolution: 0.25 Hz 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 paste TS

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

Page	Line	Correction	. Error
355	left ↓11	filter paper for quantitative analysis	filter paper for volumetric analysis

# Official Monographs

Barium Sulfate 硫酸バリウム

Page	Line	Correction	Error
473	right ↓16	filter paper for quantitative analysis	filter paper for assay

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 quantitative analysis	filter paper for assay

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 quantitative analysis	filter paper for assay

Candesartan Cilexetil カンデサルタンシレキセチル

~	andesartan chekem yeryymyt et t					
	Page	Line	Correction	Еггог		
			the area of the peak other than candesartan	the area of the peak other than candesartan		
			cilexetil and the peaks mentioned above from	cilexetil and the peaks mentioned above from		
	565	right ↓ 2	the sample solution is smaller than 1/10 times	the sample solution is <u>not</u> smaller than 1/10		
-			the peak area of candesartan cilexetil from the	times the peak area of candesartan cilexetil		
			standard solution,	from the standard solution,		

Diflorasone Diacetate ジフロラゾン酢酸エステル

	Page	Line	Correction	Error
	<b>700</b>		6α,9-Difluoro-11β,17,21-trihydroxy-16β-meth	6α,9-Difluoro-11β,17,21-trihydroxy-16β-meth
	792	right ↓ 4	ylpregna-1,4-diene-3,20-dione 17,21-diacetate	ylpregna-1,4-diene-3,20-dione 17,21-diaceate

Docetaxel Injection ドセタキセル注射液

Page	Line Correction Error								
822	right ↑21		It contains not $\underline{\text{more}}$ than 93.0% and not $\underline{\text{less}}$ 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

Γ	Page	Line	Correction	Error
,	823	right ↑27	It contains not less than 93.0% and not more than 105.0% of the labeled amount of docetaxel (C <sub>43</sub> H <sub>53</sub> NO <sub>14</sub> : 807.88).	It contains not $\underline{\text{more}}$ than 93.0% and not $\underline{\text{less}}$ 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

آ	Page	Line	Correction	Error				
	836	left   20	$= M_{\rm S} \times A_{\rm T}/A_{\rm S} \times \underline{V''/V} \times 1/C \times 45$	$= M_{\rm S} \times A_{\rm T}/A_{\rm S} \times \underline{V/V'} \times 1/C \times 45$				

Ebastine エバスチン

Page	Line	Correction	Error		
046	left ↓ 19	with exactly 10 μL each of the sample solution	with exacty 10 μL each of the sample solution		
846		and standard	and standard		

Ergometrine Maleate エルゴメトリンマレイン酸塩

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

Heparin Calcium ヘパリンカルシウム

Page	Line	Correction	Еггог			
1009	right ↑5	(antifactor IIa activity) per mg and not less	It contains not less than 180 Heparin Units (antifactor IIa activity) per mg. calculated on the dried basis, 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, D-sorbitol ar						Separately, weigh <u>exacty</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 quantitative analysis	filter paper for assay			

Methylergometrine 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 <u>R</u> )-N-[(1S)-1-(Hydroxymethyl)propyl]-6-met hyl-9,10-didehydroergoline-8-carboxamide monomaleate	(8 <u>S</u> )- <i>N</i> -[(1 <i>S</i> )-1-(Hydroxymethyl)propyl]-6-met hyl-9,10-didehydroergoline-8-carboxamide monomaleate

Noscapine ノスカピン

Page	Line	Correction				Correction Error					
		Spray	evenly	dilute	bismuth	Spray	evenly	dilute		bismuth	
1327	left ↑18	subnitrate-potassium iodide TS for spraying on			subnitrate	e-potassium	iodide TS	for	spray on		
		the plate:				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 exacty 10mL of diluted nitric acid (1 in 100)

Pipemidic Acid Hydrate ピペミド酸水和物

ĺ	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 and in ethanol (99.5).	

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-sodium hydroxide-ethanol 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 exactly 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 Achyranthes fauriei H. Léveillé et Vaniot or Achyranthes bidentata Blume (Amaranthaceae).	Achyranthes Root is the root of Achyranthes fauriei Leveillé et Vaniot or Achyranthes bidentata Blume (Amaranthaceae).

Mentha Herb ハッカ

Page	Line	Correction	Error
1914	right ↑15	Spray evenly 4-methoxybenzaldehyde-sulfuric acid-acetic acid-ethanol TS for spraying 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	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
		standard solution.	solution.

Peony Root シャクヤク

Page	Line	Correction	Error
1936	left ↓12	6 times with 10 µL of the standard solution under the above operating conditions, the	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	6 times with $10 \mu L$ of the standard solution under the above operating conditions, the	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
Ī	2280		240.0	220.0

# General Information / Biotechnological/Biological Products

SDS-Polyacrylamide Gel Electrophoresis

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

# General Information / Crude Drugs

Scientific Names used in the JP and Those being used Taxonomically

~	distribution of the state of th						
	Page	Line	Correction	Error			
	0.501	1 12	Achyranthes fauriei H. Léveillé et Vaniot	Achyranthes fauriei Leveille et Vaniot			
	2521	↓ 12	=Achyranthes fauriei H. Lev. & Vaniot	=Achyranthes fauriei H. Lev. & Vaniot			

Purity Tests on Crude Drugs using Genetic Information

Page	Line	Correction	Error
2516	right ↓ 17	related species using the <u>internal</u> transcriber space (ITS) region of the rDNA region, since	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.