

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。



JP17 table of errata

November 17, 2017

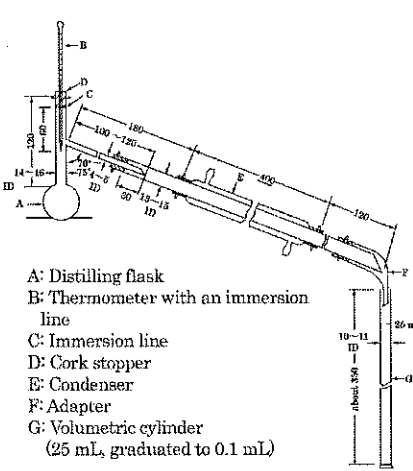
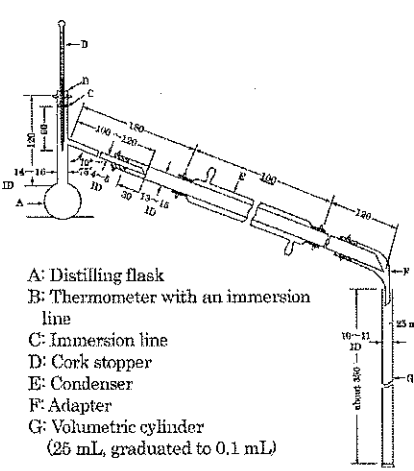
Preface

| 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. |

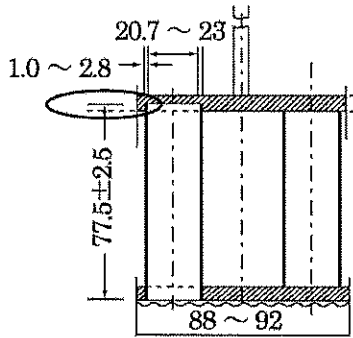
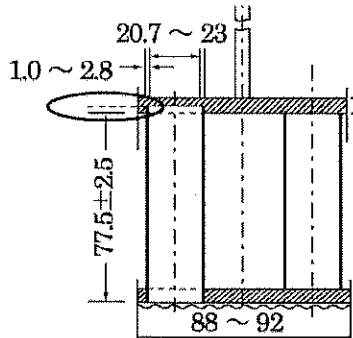
General Tests / 2.57 Boiling Point and Distilling Range Test

| 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_{20}^{20} : 1.450 – 1.455 |
| 207 | left ↑ 3 | <i>Artemisia argyi</i> for purity test Powder of the leaf and twig of <i>Artemisia argyi</i> H. Léveillé et Vaniot (<i>Compositae</i>). | <i>Artemisia argyi</i> 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 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 <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 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 Hz 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-diacetate | 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>exactly</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 <i>R</i>)- <i>N</i> -[(1 <i>S</i>)-2-Hydroxy-1-methylethyl]-6-methyl-9,10-didehydroergoline-8-carboxamide monomaleate | (8 <i>S</i>)- <i>N</i> -[(1 <i>S</i>)-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> |

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 <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> H. Léveillé et Vaniot or <i>Achyranthes bidentata</i> Blume (<i>Amaranthaceae</i>). | Achyranthes Root is the root of <i>Achyranthes fauriei</i> Leveillé 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 R _f 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 R _f value with the spot obtained from the standard solution. |

Peony Root シヤクヤク

| 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 シヤクヤク末

| 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> Leveillé 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. |