

PSEHB Notification No. 1210-1

December 10, 2019

To: Prefectural Governors

Director-General of Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Partial Revision of “Japanese Pharmaceutical Excipients 2018”

The standards for pharmaceutical excipients are provided in Attachment entitled “Japanese Pharmaceutical Excipients 2018” (hereinafter referred to as “JPE 2018”) of the notification “On Japanese Pharmaceutical Excipients 2018” (PSEHB Notification No. 0329-1 issued by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, the Ministry of Health, Labour and Welfare dated March 29, 2018).

We hereby notify a partial revision of JPE 2018 as attached.

We ask you to understand an outline of the partial revision of JPE 2018 shown below together with the attachment and inform those of the relevant parties and organizations.

[Notice]

No. 1 Outline of the partial revision of JPE 2018

1 In General Tests, Processes and Apparatus, the following revisions were made:

(1) The following item was newly added:

1) Test Methods

(2) The following items were revised:

1) Reagents, Test Solutions

2) Standard Solutions for Volumetric Analysis

3) Standard Solutions

2 In the monographs of JPE 2018, the following revisions were made:

(1) The following item was added:

1) D-Mannitol, Low Substituted Hydroxypropylcellulose and Fully Hydrolyzed Polyvinyl Alcohol Granules

- (2) The specifications, etc. of the following items were revised:
- 1) Acesulfame Potassium
 - 2) Acrylic Acid and Octyl Acrylate Copolymer
 - 3) Cellulose Acetate
 - 4) Cetanol and Polyethyleneglycol Monostearate Mixed Wax
 - 5) Cetanol and Polysorbate 60 Mixed Wax
 - 6) Cetostearyl Alcohol and Sodium Cetostearyl Sulfate Mixture
 - 7) Cetostearyl Alcohol and Sodium Lauryl Sulfate Mixture
 - 8) Coconut Fatty Acid Diethanolamide
 - 9) *N*-Cocoyl-L-Arginineethylester DL-Pyrrolidonecarboxylate
 - 10) Decyl Oleate
 - 11) Diethyl Sebacate
 - 12) Diisobutyl Adipate
 - 13) Diisopropyl Adipate
 - 14) Diisopropyl Sebacate
 - 15) Dimethylpolysiloxane (Oral Use)
 - 16) Dimethylsiloxane and Methyl (Polyoxyethylene) Siloxane Copolymer
 - 17) Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion
 - 18) 2-Ethylhexyl Acrylate, 2-Ethylhexyl Methacrylate and Dodecyl Methacrylate Copolymer Solution
 - 19) 2-Ethylhexyl Acrylate and Vinylpyrrolidone Copolymer Solution
 - 20) Ethylmaltol
 - 21) Fumaric Acid, Stearic Acid, Polyvinylacetal Diethylaminoacetate and Hydroxypropylmethylcellulose 2910 Mixture
 - 22) Geraniol Denatured Alcohol (95 vol%)
 - 23) Geraniol Denatured Alcohol (99 vol%)
 - 24) 2-Hexyldecanol
 - 25) Hexyl Laurate
 - 26) Hydroxypropylmethylcellulose 2910, Titanium Dioxide and Macrogol 400 Mixture
 - 27) Isostearic Acid
 - 28) Lactose and Microcrystalline Cellulose Spheres
 - 29) Lanolin, Hydrogenated
 - 30) Linear Alkylbenzene

- 31) Liquid Lanolin
- 32) Liquid Sugar
- 33) Maleic Acid
- 34) D-Mannitol, Carmellose, Microcrystalline cellulose and Crospovidone Mixture
- 35) D-Mannitol, Xylitol, Microcrystalline Cellulose, Crospovidone and Anhydrous Dibasic Calcium Phosphate Mixture
- 36) D-Mannitol, Xylitol, Microcrystalline Cellulose, Crospovidone and Magnesium Aluminometasilicate Mixture
- 37) Methyl Vinyl Ether and Maleic Anhydride Copolymer
- 38) Microcrystalline Cellulose and Carmellose Sodium
- 39) 2-Octyldodecanol
- 40) 2-Octyldodecyl Myristate
- 41) Oleyl Alcohol
- 42) Oleyl Oleate
- 43) Phytic Acid
- 44) Polydimethylsiloxane and Silicon Dioxide Mixture
- 45) Polyoxyethylene Arachyl Ether and Stearyl Alcohol Mixture
- 46) Polyoxyethylene Glyceryl Monococoate (7 E.O.)
- 47) Polyvinyl Alcohol and Polyethylene Glycol Graft Copolymer
- 48) Polyvinyl Alcohol, Acrylic Acid and Methyl Methacrylate Copolymer
- 49) Silver Leaf
- 50) Sodium Caseinate
- 51) Sodium Lauryl Phosphate and Glyceryl Monostearate Mixture
- 52) Sodium *N*-Cocoyl-*N*-methylaminoethylsulfonate
- 53) Sodium Stearyl Fumarate
- 54) Styrene, Isoprene and Styrene Block Copolymer
- 55) Sucrose and Starch Spheres
- 56) Synthetic Aluminum Silicate, Hydroxypropyl Starch and Crystalline Cellulose
- 57) Vinyl Acetate and Crotonic Acid Copolymer
- 58) Zein

No. 2 Schedule of Enforcement

This notification shall be applied on December 10, 2019. However, the standards then in force may remain applicable before and on June 30, 2021.