

PSEHB Notification No. 0307-1

March 7, 2022

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 accordance with the establishment of the Japanese Pharmacopoeia 18th edition, the general notices of JPE 2018 were revised.
- 2 In General Tests, Processes and Apparatus, the following revisions were made:
 - (1) The following items were revised.
 - 1) Reagents, Test Solutions
 - 2) Standard Solutions
- 3 In the monographs of JPE 2018, the following revisions were made:
 - (1) The specifications, etc. of the following items were revised.

- 1) Carboxyvinyl Polymer
- 2) Diethyl Phthalate
- 3) Glyceryl Monomyristate
- 4) Glyceryl Monooleate
- 5) Glyceryl Monostearate, Self-emulsifying Type
- 6) Hard Fat
- 7) Hydrophilic Hydrocarbon Gel
- 8) Maleated Rosin Glycerin Ester
- 9) D-Mannitol and Corn Starch Granules
- 10) Medium Chain Fatty Acid Triglyceride
- 11) Methacrylic Acid Copolymer LD
- 12) 2,2',2''-Nitrilotriethanol
- 13) Peru Balsam
- 14) Polyoxyethylene Castor Oil
- 15) Polyoxyethylene Glyceryl Monococoate (7E.O.)
- 16) Polyoxyethylene Glyceryl Triisostearate
- 17) Polyoxyethylene Hydrogenated Castor Oil 5
- 18) Polyoxyethylene Hydrogenated Castor Oil 10
- 19) Polyoxyethylene Hydrogenated Castor Oil 20
- 20) Polyoxyethylene Hydrogenated Castor Oil 40
- 21) Polyoxyethylene Hydrogenated Castor Oil 50
- 22) Polyoxyethylene Hydrogenated Castor Oil 60
- 23) Polyoxyethylene Hydrogenated Castor Oil 100
- 24) Polyoxyl 35 Castor Oil
- 25) Polyvinyl Chloride
- 26) Sucralose
- 27) α -Thioglycerol
- 28) Triacetine
- 29) Wheat Germ Oil

No.2 Schedule of Enforcement

This notification shall be applied on March 7, 2022. However, the standards then in force may remain applicable before and on September 30, 2023.