Attachment 5

List of Documents and Procedures　(GMP)

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| Applicable part of laws and regulations | Documents/Procedures  | Name of Documents/ Procedures at the site  | Documents/ Procedures Number  | Date of latest revision (Date of enactment if no revision has been made.) | Reasons for not having documents/procedures in place (if applicable)  |
| GMP Ministerial Ordinance\* Article3-3, Paragraph 1, Item 1Promulgation notice\*\* Section 3. Explanation of each article, 5. Matters pertaining to Article 3-3 (Pharmaceutical quality system), (1) Matters pertaining to Article 3-3 Item 1 | Documents which describe the quality policy and components of the procedures for the pharmaceutical quality system, etc. (This document corresponds to the Quality Manual of the ICH Q10 Guideline and PIC/S GMP Guideline)  |  |  |  |  |
| GMP Ministerial Ordinance Article 8, Paragraph 1, Item (1)  | Procedures for Hygiene Control of buildings, facilities and personnel |  |  |  |  |
| GMP Ministerial Ordinance Article 8, Paragraph 1, Item (2)  | Procedures for Manufacturing Control describing Manufacturing process, Manufacturing facilities, Materials and Products |  |  |  |  |
| Promulgation notice Section 3. Explanation of each article, 11. Matters pertaining to Article 8 (Procedures, etc.) (1)-(2) Matters pertaining to Article 8, Paragraph 1, Item 2 ｂ.-(g)-(c) | Procedures concerning confirmation that raw materials are suitable with reference to the relevant provisions in the Japanese Standards for Biological Ingredients(When manufacturing products involving pharmaceuticals using raw materials of　human or animal origin) |  |  |  |  |
| GMP Ministerial Ordinance Article 8, Paragraph 1, Item (3)  | Procedures for Quality Control describing Testing facilities, Testing equipment, Test samples, Testing, etc. (including Procedures for handling OOS and Re-testing) |  |  |  |  |
| GMP Ministerial Ordinance Article8, Paragraph 1, Item (4)  | Procedures for Stability Monitoring |  |  |  |  |
| GMP Ministerial Ordinance Article 8, Paragraph 1, Item (5)  | Procedures for Product Quality Review |  |  |  |  |
| GMP Ministerial Ordinance Article 8, Paragraph 1, Item (6)  | Procedures for Supplier Management |  |  |  |  |
| GMP Ministerial Ordinance Article 8, Paragraph 1, Item (7)  | Procedures for Management of Outsourced activities  |  |  |  |  |
| GMP Ministerial Ordinance Article 8, Paragraph 1, Item (8)  | Procedures for Batch disposition |  |  |  |  |
| GMP Ministerial Ordinance Article 8, Paragraph 1, Item (9)  | Procedures for Validation (including Procedures for Process Validation and Procedures for Cleaning Validation) |  |  |  |  |
| GMP Ministerial Ordinance Article　8, Paragraph　1, Item　(10)  | Procedures for Change Control |  |  |  |  |
| GMP Ministerial Ordinance Article　8, Paragraph　1, Item　(11)  | Procedures for Deviation |  |  |  |  |
| GMP Ministerial Ordinance Article　8, Paragraph　1, Item　(12)  | Procedures for handling quality information (including complaint) |  |  |  |  |
| GMP Ministerial Ordinance Article　8, Paragraph　1, Item　(13)  | Procedures for Recall |  |  |  |  |
| GMP Ministerial Ordinance Article　8, Paragraph　1, Item　(14)  | Procedures for Self-inspection |  |  |  |  |
| GMP Ministerial Ordinance Article　8, Paragraph　1, Item　(15)  | Procedures for Training |  |  |  |  |
| GMP Ministerial Ordinance Article　8, Paragraph　1, Item　(16)  | Procedures for Documentation |  |  |  |  |

\*Ministerial Ordinance on Standards for Manufacturing Control and Quality control for Drugs and Quasi-drugs　（Ordinance of Ministry of Health, Labour and Welfare, No. 179, 2004）

\*\* Notification Concerning Partial Amendment of the Ministerial Ordinance on Standards for Manufacturing Control and Quality control for Drugs and Quasi-drugs (PSEHB/CND Notification No. 0428/2, April 28, 2021)