MOHW FDA No. 1091105341 Announcement dated August 31, 2020 "

Notices for the application of Plant master file" Form C -5

PMF Checklist for Foreign Pharmaceutical Manufacturers

Form C-5: Validation and Qualification (For the expansion of manufacturing site, the items which are marked with asterisk are required, and the relevant documents shall be enclosed.)

Applicant:	**Receipt No.**	**Case Number**
Item	Please complete the checklist item by item and indicate the attachment numbers or the page numbers of **submitted documents**.	reviewer comment
5. Documents for Validation and Qualification		
5.1 Provide the validation master plan.	P.	
5.2 Describe in detail the validation and qualification statuses for the following facilities and equipment used for the dosage form(s) / product(s) / operation(s) in this application.		
*5.2.1 Utility Systems (Annex 15)	P.	
*5.2.1.1 The latest qualification protocol and summary report of HVAC system.	P.	
*5.2.1.2 The latest sampling plan and summary report of water system for monitoring the water quality (including trend analysis).	P.	
*5.2.1.3 The sampling plan and summary report for monitoring the use points of product-contact gas.	P.	
*5.2.2 Validation of Computerized Systems: (Annex 11)		
*5.2.2.1 Please provide the inventory list of the computerized systems used, including the software categories and complete dates of validation.	P.	
*5.2.2.2 Please select one of the following computerized systems to provide the latest validation protocol and summary report: Environmental monitoring, production/warehouse management, or data management of laboratory.	P.	
*5.2.2.3 Brief description of the strategies to ensure data integrity	P.	

*5.3 Where apply for the aseptic preparation, give a brief description for the procedure of aseptic process simulation test (including but not limited to the frequency of implementation, the categories of the production lines, etc.). (Annex 1)	P.	
5.4 Describe the procedure for periodical verification of the ongoing process. (Annex 15). (Annex 15)	P.	
*5.5 Cleaning validation of the dosage form(s) / product(s) / operations applied for. (Annex 15)	P.	
*5.5.1 Please describe the cleaning procedure for the product-contact equipment used for the dosage form(s) / product item(s) / process operation(s) in this application. Where manual cleaning is performed, describe how to set up a justified frequency to confirm the effectiveness of the manual process.	P.	
*5.5.2 Describe the implementation of cleaning validation (e.g. single product approach or grouping approach). Where grouping approach is used, describe the categories in detail, and also list the APIs of each product in each group, and the target ingredient for cleaning validation.	P.	
*5.5.3 Provide the cleaning validation protocol, including the sampling plan (e.g. sampling points, sampling size, sampling illustrations, and sampling methods, etc.) and the acceptance criteria (including the relevant calculations with descriptions).	P.	
*5.5.4 Provide the summary report of cleaning validation (including the recovery rate of the sampling method and blank test, as well as the dirty/clean hold times).	P.	
*5.5.5 Describe the analytical method used for cleaning validation and provide the summary report of aforementioned analytical method validation. Where the analytical method refers to pharmacopoeia, provide the paper of pharmacopoeia pages, as well as the summary report for the verification of the analytical method.	P.	
	Signature (including date of signing)	