Appendix 8

Documents for the Application of Drug Review and Registration of API

Documents should be submitted	Common Pharmaceutical Preparation	API for Exportation	
		Non-counter service	Counter service[*3]
Application fees	○	○	○
Application form (original copy and duplicate copy)	○	○	○
Assurance statement (A and B)	○	○	○
Exportation assurance statement	×	○	○
Assurance statement of the application of exportation-only API (for counter service)	×	×	○
Form for sticking label and package insert (two copies)	○	○	○
Form for sticking license (one copy)	○	○	△[*4]
Photocopy of the API GMP compliance certificate issued in the past 2 years	△	×	○
Authorization letter (imported products)	○	×	×
CPP of source country (imported products)	○	×	×
Technical documents[*1]	○[*2]	○[*2]	○[*2]
Drug testing[*5]	×	×	×

Note:

○: submission is a must; ×: submission is not necessary; △: submission is on a case-by-case basis

*1 Please refer to the "technical documents for the application for review and registration of API".

*2 In principle, the number of technical documents required is 14 copies for common API and 2 copies for exportation purpose.

*3 Applicants are restricted to manufacturers who passed the API GMP compliance assessment within two years before the date of application.

*4 Applications with valid API licenses are exempt from data submission.

*5 According to Article 24 Paragraph 2, the assessment can be done through dossier review instead of sample testing, except for those cases deemed by the central health competent authority as drug testing being necessary.