Appendix 8

Documents for the Application of Drug Review and Registration of API

Documents should be submitted (Note3)	For Common Pharmaceutical Preparation	API for Exportation
Application fees	○	○
Application form (original copy and duplicate copy)	○	○
Assurance statement (A and B)	○	○
Assurance statement for exportation	╳	○
Label and package insert sticking form (two copies)	○	○
License sticking form (one copy)	○	○
Photocopy of the API GMP compliance certificate dated within the past 2 years	○	○
Authorization letter (imported products)	○	╳
Technical documents (Note1)	○	○
Drug testing results/reports (Note2)	╳	╳

Note:

○: submission required; ╳: not required; △: submission is on a case-by-case basis

1 Please refer to the “technical documents for the application for review and registration of API, Appendix 9”.

2 According to Article 24 Paragraph 2, the assessment of product quality can be performed through dossier review instead of physical sample testing, except for those cases being requested by the central competent health authority to have physical testing on products.

3 Application dossiers shall be submitted according to the Common Technical Document (CTD) format.