Appendix 4:
Documents for the Application for Drug Review and Registration of Generics

Documents (Note4)	Generics			
	Medical gas		Generic drug other than medical gas	
	Domestic products	Imported products	Domestic products	Imported products
Application fees	○	○	○	○
Application form (original copy and duplicate copy)	○	○	○	○
Assurance statement (A)	○	○	○	○
Assurance statement (B)	○	○	○	○
Label and package insert sticking form (two copies)	○	○	○	○
License sticking Form	○	○	○	○
Manufacturing and Control Standards report and the amount of all components in the batch record or batch records of the same lot as the finished product of the tentative production batch	○	○	○	○
Technical documents of active pharmaceutical ingredients (Note3)	×	○	○	○
Specifications, testing methods and results for excipients	○	○	○	○
Specifications, testing methods and results for final products (Note5)	○	○	○	○
Stability study reports/results	△	△	○	○
Photocopy of GMP compliance certificate	○ Note 1	○ Note 1	○	○
CPP of source country	×	○	×	○

Authorization letter	╳	○	╳	○
Validation report of analytical methods	○ Note 1	○ Note 1	○	○
Validation report of critical manufacturing process	○ Note 1	○ Note 1	○	○
BE study, or BA study and Clinical trials reports	╳	╳	○ Note 1, 11, 12	○ Note 1, 11, 12
Drug testing reports/ result(Note2)	╳	╳	╳	╳

Note:

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

1. Pursuant to relevant regulations promulgated by central competent health authority.
2. According to Article 24 Paragraph 2, except for those cases being requested tohave testing on drug products by central competent health authority, the assessment of quality can be performed through dossier review instead of physical sample testing.
3. Technical documents of active pharmaceutical ingredients can be substituted by other dossier as promulgated by the central competent health authority.
4. Application dossiers shall be submitted according to the Common Technical Document (CTD) format.
5. Applications for the registration of pharmaceutical products with hard capsules, one of the following documents shall be provided for its review:
   (1) For using domestic manufacturing hard capsules, the license number of the hard capsule shall be provided.
   (2) For using imported hard capsules:
   The composition of the hard capsule (name and content) shall be listed in the CTD format 3.2.P.1, and the information of specifications, analytical procedures, validations of analytical procedures (the validation test can be waived if the analytical method followed the pharmacopoeia), certificates of analysis, and BSE/TSE statements regarding excipients of animal origin etc. shall be described in the CTD format 3.2.P.4.
6. For a registration application of the controlled drugs manufactured in Taiwan, either the API approval of the controlled drugs or the approval of its legal use should be included.
7. Stability study documentation includes one copy each of the written operation

procedures, testing report, quantitative analytical methods and their validation reports.

8. For sterile preparation, the validation report of critical manufacturing processes should include sterilization validation.
9. For toll manufacturing or contract testing products, the contracts should be included.
10. Medical gas refers to CO2, O2 or N2O that are for medical uses with the purity above 99.0%v/v. For CO2 and O2 generated from the air, the stability study reports can be exempt from submission; whilst the documents should be retained for future inspection.
11. Application for generic drugs license within 5 years of the issuing date of the first new drug license, then local clinical trial reports (including bridging study) meeting the standards that its reference was provided in the original license-granted the NDA should be submitted. If local clinical trial reports (including bridging study) were not in the dossier for the approval of this new drug, one of the following documents should be submitted, (1) BE study report, or (2) BA study and clinical trials reports. Application for generic drugs license out of 5 years of the issuing date of the first new drug license, either (1) BE study reports, or (2) BA study and clinical trial reports should be submitted.
12. Unless otherwise provided, the requirement for the bioequivalence study or the bioavailability and clinical study report may be waived for drug products that category in the Guidelines on the Review of Over-the-counter Drugs or in the category of the preparations of inherited formulation.
13. Waiver or replacement of the bioavailability or bioequivalence test can follow Article 8 of the Regulations of Bioavailability and Bioequivalence Studies, or contents approved or relevant regulations promulgated by central competent health authority.