(Appendix 10 Documents Required for the Application for Drug Review and Registration of Radiopharmaceutical Drugs

Technical document	According to the regulations set out in Appendix 11		
Drug testing (Note5)	×	×	×
CPP (Note4)	×	○	×
Document of stability study	○	○	○
Validation document of critical manufacturing processes (Note3)	○	○	○
Validation document of analytical methods	○	○	○
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	○	○	○
Testing specifications, methods and results of final products	○	○	○
Testing specifications, methods and results of excipients	○	○	○
Testing specifications, methods and results of active pharmaceutical ingredients (Note7)	○	○	○
Photocopy of GMP compliance certificate	○	○	○
Formulation basis (Note2)	○	×	○
CPP of source country (Note1)	×	○	×
Authorization letter	×	○	×
Form for sticking license	○	○	○
Form for sticking label and package insert (two copies)	○	○	○
Assurance statement A & B	○	○	○
Application form (original copy and duplicate copy)	○	○	○
Application fees	○	○	○
Documents to be submitted (Note8)	Local products	Imported products	Local products
	New drugs		New Dosage Form

(	Imported products	○	○	○	○	○	○	○	×	○	○	○	○	○	○	○	○	×	×	
News Dose	Local products	○	○	○	○	○	×	×	○	○	○	○	○	○	○	○	○	×	×	
	Imported products	○	○	○	○	○	○	○	×	○	○	○	○	○	○	○	○	×	×	
Generic	Local products	○	○	○	○	○	×	×	○	○	○	○	○	○	○	○	○	×	×	(Note6)
	Imported products	○	○	○	○	○	○	○	×	○	○	○	○	○	○	○	○	×	×	

Note:

○: submission is a must; ×: submission is not necessary

1 If the source country’s CPP does not state the complete site address, a copy of the latest GMP site inspection report must be provided. (If the

(missing information is of minor detail, such as the post code or district name, then an explanation letter issued by the original manufacturer will be sufficient).

2 The submission of formulation basis is not required for preparations of new radiopharmaceuticals, new dosage forms, new administration doses or new unit strength that have been developed in Taiwan. However, the study of formulation design and related technical documents should be provided additionally.

3 If the application product is an imported sterile preparation, then the documents of critical manufacturing process should include sterilization validation.

4 For radiopharmaceuticals manufactured in Taiwan, new dosage form, new administration dose and new unit strength, the applicant should submit studies of formulation design.

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.

6 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.

7 Not applicable for those pharmaceutical products which technical documents can be substituted by other dossier announced by the central competent health authority.

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