Appendix 11

Technical Documents Required for the Application for Drug Review and Registration of New Drugs, New Dosage Forms and New Dose of Radiopharmaceutical Drugs

Type of documents		Origin, discovery process and uses	Testing methods and specifications of physicochemical properties				Non-clinical animal study report										Clinical trial report (please compile the report and prepare a summary)		Radiation dosage study report
							Safety study report					Efficacy study		PK study					
Drug data/ category		Origin, discovery process Uses in other countries Properties and a comparison with other drugs	Structure physicochemical properties	Testing specifications and methods	Content uniformity test Dissolution test	Provision of new API or reference product	Single dose toxicity test	Repeated dose toxicity test	Antigenicity	Embryo test, dependency test, mutagenicity, carcinogenicity, local tolerance	Radio biological study	Effectiveness study	General pharmacologic study	Absorption, distribution, metabolism, excretion	BE study, BA study	Design and results of clinical trials	Literature review and citation	
New ingredient	For diagnoses	○	○	○	△	○	○	△	△	×	×	○	×	○	×	○	○	○
	For treatment	○	○	○	△	○	○	△	△	△	○	○	△	○	×	○	○	○

Documents should be submitted for the NDA of radiopharmaceutical drugs

Documents for the applications of new dosage form and new dose of radiopharmaceutical drugs	New administration route	○	×	○	△	×	×	×	×	×	×	×	×	△	△	△	△	△	○
	New indication	○	×	○	×	×	×	×	×	×	×	○	×	×	×	△	△	△	○
	New dosage form	○	×	○	△	×	×	×	×	×	×	×	×	△	△	△	△	△	○
	New dose	○	×	○	×	×	×	×	×	×	×	×	×	×	×	△	△	△	○

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