

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

[illegible]

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

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

Note :

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