Appendix 3:

Technical Documents for the Application for Drug Review and Registration of New Drugs, New Dosage Forms, New Administration Doses and New Unit Strengths

		Origin, discovery process and uses in other countries			Physico-chemical properties		Safety study report									Pharmacological effects		Absorption, distribution, metabolism and excretion study (animals/ humans)				Clinical trial report			
		Origin and the discovery process	Uses in other countries	Comparison of properties	Structure	Physicochemical properties	Acute toxicity	Subacute toxicity	Chronic toxicity	Embryo test	Dependency	Antigenicity	Mutagenicity	Carcinogenicity	Local tolerance	Evidence of effectiveness	General pharmacology	Absorption	Distribution	Metabolism	Excretion	BA	BE	Other clinical trials	Medical journals
New Drugs	New ingredients	○	○	○	○	○	○	○	○	○	△	△	△	△	△	○	○	○	○	○	○	○	△	○	△
	Liposome	○	○	○	○	○	○	○	○	○	△	△	△	△	△	○	○	○	○	○	○	○	△	○	△
	Transdermal absorption	○	○	○	○	○	○	○	○	○	△	△	△	△	○	○	○	○	○	○	○	○	△	○	△
	New administration route	○	○	○	╳	╳	○	○	△	△	╳	△	╳	╳	△	○	△	○	○	○	○	○	╳	○	△
	Liposome	○	○	○	╳	╳	○	○	○	○	╳	△	╳	╳	△	○	△	○	○	○	○	○	╳	○	△
	Transdermal absorption	○	○	○	╳	╳	△	△	△	△	╳	╳	╳	╳	○	○	△	○	○	○	○	○	╳	○	△
	New efficacy	○	○	○	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	○	△	△	△	△	△	△	╳	○	△
	Liposome	○	○	○	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	○	△	△	△	△	△	△	╳	○	△
	Transdermal absorption	○	○	○	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	○	△	╳	╳	╳	╳	△	╳	○	△
	New compound	○	○	○	╳	╳	○	○	△	△	╳	╳	╳	╳	△	○	○	○	○	○	○	○	╳	○	△

	Liposome	○	○	○	╳	╳	○	○	○	╳	╳	╳	╳	╳	△	○	○	○	○	○	○	○	○	○	△
	Transdermal absorption	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	○	○	○	○	○	○	○	○	○	○	△
New dosage form, new administration dose, new unit strength	New dosage form (controlled release)	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	◎	◎	◎	△
	New dosage form (immediate release)	○	○	○	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	╳	◎	◎	◎	△
	Liposome	○	○	○	╳	╳	○	○	○	○	╳	△	╳	╳	△	○	╳	○	○	○	○	◎	◎	◎	△
	Transdermal absorption	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	○	╳	╳	○	╳	╳	╳	◎	◎	◎	△
	New administration dose	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	△	○	╳	○	○	○	○	○	╳	○	△
	Liposome	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	△	○	╳	○	○	○	○	○	╳	○	△
	Transdermal absorption	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	△	○	╳	╳	╳	╳	╳	○	╳	○	△
	New unit strength	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	△	╳	╳	╳	╳	╳	╳	◎	◎	◎	╳
	Liposome	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	△	╳	╳	╳	╳	╳	╳	◎	◎	◎	╳
	Transdermal absorption	○	○	○	╳	╳	△	△	△	╳	╳	╳	╳	╳	△	╳	╳	╳	╳	╳	╳	◎	◎	◎	╳

Note:

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

◎: Using either one of the following methods: (1) BE study; (2) BA and clinical trials.

1 If there are efficacy or safety concerns over the application drugs, related documents should be provided additionally at the central health

competent authority’s request.

2 Other clinical trial reports should comply with the regulations announced by the central health competent authority.

3 Medical journals refer to clinical documents and reports.

4 Products developed locally do not need to submit documents of “Uses in other countries”.

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

6 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.