Appendix 5

Technical Documents for the Application for Drug Review and Registration of Generics in the Dosage Forms of Liposome or Transdermal Absorption

	Origin, discovery process and uses in other countries			Physico-chemical properties		Safety study report								Pharmacological effects		Absorption, metabolism and excretion study (animals/ humans)				Clinical study 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
Liposome																								
Generic (i)	×	×	×	×	×	△	△	△	×	×	×	×	×	△	×	×	△	△	△	△	◎	◎	◎	×
Generic (ii)	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	◎	◎	◎	×
Transdermal absorption dosage form																								
Generic	×	×	×	×	×	×	×	×	×	×	×	×	×	○	×	×	×	×	×	×	◎	◎	◎	×

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.

Generic (i): generics with the same active ingredients, but using excipients different in composition and proportion.

Generic (ii): Generics identical in active ingredients, excipients and their proportion.

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