LAO PEOPLE'S DEMOCRATIC REPUBLIC

PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY

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Checklist of Requirements for the Registration of Import Pharmaceutical Product

Item	Parameters	Copies	FDD use only
PART I.	**ADMINISTATIVE AND PRESCRIBING INFORMATION**		
Section A	FDD Application Form No. 2		
Section B	Applicant nomination certified by the manufacturer of the Product Supplementary Documentation		
Section C	Stage 1 Approval Letter		
	Certificate of Pharmaceutical Product (CPP)		
	Certificate of Drug Registration (CoR)		
	Certificate of Good Manufacturing Practice (GMP)		
	Certificate of Free sale (CFS)		
	Summary of Product Characteristics		
PART II.	**Quality Documents**		
Section A	Tablet of contents		
Section B	Quality of contents		
	Body of Data		
	- Drug Substance		
	- Drug Product		
	- List of Key Literature Reference		
PART III.	**Non Clinical Document**		
Section A	Table of contents		
Section B	Non-clinical Overview		
Section C	Non-clinical Written and Tabulated Summaries		
	- Table of Contents		
	- Introduction		
	- Pharmacology Written Summary		
	- Pharmacology Tabulated Summary		
	- Pharmacokinetics Written Summary		
	- Pharmacokinetics Tabulated Summary		
	- Toxicology Written Summary		
	- Toxicology Tabulated Summary		
Section D	Non-Clinical Study Summary		
Section E	List of Key Literature Reference		
PART IV.	**Clinical Document**		
Section A	Table of Contents		
Section B	Clinical Overview		
Section C	Clinical Summary		
	- Summary of Bio-Pharmaceutics and		
	- Associated Analytical Methods		
	- Summary of Clinical Pharmacology Studies		
	- Summary of Clinical Efficacy		
	- Summary of Clinical Safety		
	- Tabulated Listing of all Clinical Studies		
	- List of Key Literature References		
	- Published Clinical Paper		

Note: Data to be submitted will be based on each application type as follow:

New Product - Parts I to IV (except for existing chemical or biological entity (s) in a new dosage form which will require only **Parts I & II, together with pharmacokinetic data)**

Generic product-**Parts** I & II