LAO PEOPLE'S DEMOCRATIC REPUBLIC
PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY

APPLICATION FOR VARIATION OF REGISTERED TRADITIONAL MEDECINE AND HEALTH SUPPLEMENT PRODUCTS

The company/Factory name:	
Product Category:	**□ Traditional Medicine** **□ Health Supplement**
Product Registration No.	

Tick (✓) on the variation changes required Multiple selections are allowed.

No.	MAJOR VARIATION (MaV)	Tick
MaV-1	Change and/or addition of indication/dosing regimen/patient population	
MaV-2	Change of product labeling(subject to labeling requirements as per Drug registration Guidance Document)	
MaV-3	Change of the specification of drug substance(active ingredient) a/ Widening of limits b/ Removal of test parameter	
MaV-4	Change of the manufacturing site of the drug product	
MaV-5	Replacement of site for primary packaging(direct contact with drug product)	
MaV-6	Change in the manufacturing process for drug product	
MaV-7	Change of the specification of drug product a/ Widening of limits b/ Removal of test parameter	
MaV-8	Qualitative or quantitative change of excipient	
MaV-9	Change in color, size and/or source of hard capsule shell	
MaV-10	Change in primary packaging material a/ Qualitative and quantitative composition and /or b/ Type of container and/or c/ Inclusion of new primary packaging material	
MaV-11	Change of overage of drug substance(active ingredient)	
MaV-12	Change of shelf-life of the drug product	
MaV-13	Change of storage conditions of the drug product	
	MINOR VARIATION PRIOR APPROVAL(MiV-PA)	
MiV-PA1	Change of Drug Product name	
MiV-PA2	Change a consumer Medication Information Leaflet	
MiV-PA3	Change and /or addition of manufacturer/manufacturing site/supplier of a/ Drug substance(active ingredient) b/ Excipients in premixed form	
MiV-PA4	Change of the specification of drug substance(active ingredient) a/ Tightening of limits b/ Addition/replacement of new test parameter	

MiV-PA5	Replacement of the company or party responsible for batch release	
MiV-PA6	Change of the specification of drug product a/ Tightening of limits b/ Addition/replacement of new test parameter	
MiV-PA7	Change of the specification of drug substance(active ingredient)/drug product within compendia limits	
MiV-PA8	Change of in-process controls applied during the manufacture of the drug product (including tightening and addition of new in-process test)	
MiV-PA9	Change of batch size of drug product	
MiV-PA10	Change of imprints, bossing or other marking on tablets or printing on capsules including addition or change of inks used for product marking	
MiV-PA11	Change in the test procedure of the drug product(including replacement or addition of a test procedure)	
MiV-PA12	Replacement of a manufacturer for secondary packaging/repacked	
MiV-PA13	Change of pack size/fill volume/carton pack sizes and/or change of shape or dimension of container or closure	
MiV-PA14	Change in secondary packaging or any part of the primary packaging material not in contact with the finished product formulation such as color of flip-off caps	
MiV-PA15	Addition or replacement of measuring device for oral liquid dosage forms and other dosage form	
MiV-PA16	Change of dimensions and/or shape of tablets, suppositories or peccaries without change in qualitative and quantitative composition and mean mass	
	MINOR VARIATION NOTIFICATION(MiV-N)	
MiV-N1	Change of details of product registration holder	
MiV-N2	Change of importer and/or store address	
MiV-N3	Change of product owner	
MiV-N4	Change in ownership of manufacturer	
MiV-N5	Change of the name or address(for example postal code, street name)of the manufacturer of drug product	
MiV-N6	Change of the name or address(for example postal code, street name)of the company or manufacturer responsible for batch release	
MiV-N7	Withdrawal/deletion of the alternative manufacturer/manufacturing site/supplier of drug substance(active ingredient)	
MiV-N8	Deletion of pack size for a drug product	

Kindly specify the All the affected fields and their relevant details using the format below

Table I			
Field	**Existing data**	**Proposed change data**	**Reason for change**

Tick (✓) on the documents attached, Multiple selections are allowed

No.	Attached Supporting Documents	Tick
1	Letter of Authorization from Product Holder(For Variation of Product Name only)	
2	CoA of finish product/Free sale Certificate	
3	Batch Manufacturing Formula	
4	Manufacturing Process Documentation	
5	In Process Quality Control	
6	Finish product Specification Documentation	
7	Stability Data	
8	Attachment Container Type	
9	Proposed and Current Existing Labels For Immediate Container	
10	Proposed and Current Existing Labels For Outer Carton	
11	Proposed and Current Existing Package Inserts	
12	Letter of Authorization from Product Owner	
13	Letter of Appointment of Contract Manufacturer from Product Owner	
14	Letter of Acceptance From Contract Manufacturer	
15	GMP of Manufacturers	
16	Other Supporting Documentations; Please Specify …… ……	

Signature of Applicant	……..
Full name of Applicant	……..
Company name and Company official Stamp	
Address	
Telephone No.	
Email address:	