National Medicines Regulatory Authority
No: 120, Norris Canal Road, Colombo 10, Sri Lanka

Telephone: +94 112 698 896/7 **Fax:+94 112 689 704** **Web: www.cdda.gov.lk**

Check List for Evaluation of Borderline Products

1. Application Number:
2. Classification Number:
3. Date of application submit to the NMRA:
4. Date taken for evaluation:
5. Authorization letter addressed to CEO / NMRA by the Manufacturer: Yes / No
6. Sample Import License: Yes / No
7. Whole Sale License : Yes / No

6. Brand Name of the Product:			
7. Borderline Product:			
8. Registration status:	New	RR	
9. Route of administration:		Dosage Form (If applicable only)	
10. Type of product:	Medicine and Food	Medicine and Medical Device	Medicine and Cosmetic

11. Details of the Marketing Authorization holder (Applicant) in Sri Lanka	
Name of the applicant	
Address of the applicant	

12.Details of the Manufacturer (Please " √ " where needed)				
Manufacturer Name				
Actual manufacturer	Contract manufacturer		Other	
Address of the Manufacturing Site		Other address		
13. Is this product registered and marketed in the country of manufacture ("√")	Registered		Marketed	
	Yes	No	Yes	No
Classification of the product in country of manufacture (Please "√")				
Borderline Product				
Complementary medicine				

Health supplement	
Listed product	
Cosmetic Product	
Traditional Medicines	
Medical Device (Type of classification if any)	
Other (specify)	
Comments:	

14. Product Indications /Usage (functions/ claims)				
If it is a Device				
Does this product require dedicated instrumentation?	If Yes		Details	
Availability of User Manual	Yes	No	Manual version no /s	
Comment:				

15. Status of the Product in reference countries	Registered		Marketed		Product Classification
	Yes	No	Yes	No	
i. Australia					
ii. Canada					
iii. European Union (EU)					
iv. Japan					
v. New Zealand					
vi. Singapore					
vii. UK					
viii. USA					
ix. Malaysia					
x. Thailand					
xi. India					
Any other (specify)					

16. Finished Product details (Please "√ ")	Yes	No
16.1 Original Certificate of Pharmaceutical Product (COPP)		

Valid at the point of submission		
16.2 Original Certificate of Free Sale (CFS)		
Valid at the point of submission		
16.3 Certificate of Good Manufacturing Practice (GMP) / ISO certificate		
16.4. Formulation of the Finished Product		
Master formula (Approved master formula issued by classification stage)		
Manufacturing formula with batch size		
Validated testing procedure for finished product		
Validation report		
Manufacturing process or flow diagram		
Comment:		

16.5. Quality Control

Please "√ "	Certificate of Analysis (COA)		Stability Report	
	Yes	No	Yes	No
Appearance				
Chemical Assay for active ingredients				
Limits for heavy metals				
Limits for microbial contamination				
Disintegration test				
Any other specific test				
Comment:				

*Complete original real time stability data should be submitted at least for two commercial batches after 2 years of the product registration. Failure on submission will cause the product to be suspended until the complete documents are submitted; the registration of the product will be terminated if the complete documents still cannot be produced upon renewal of product registration.

17. Efficacy data if available

	Yes	No
Published reports		
Detail Clinical trial report for the product if available		
Comment:		

18.Composition per dosage form (Tablet/ Capsule/Gel, etc)

Write the dosage and the strength (if required)

Name of the ingredient	Botanical name (if available)	Amount	Function
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

19. Instrument with standard accessories and spare parts (If applicable)		
Name of the accessory / spare part	Catalogue number	Function
1		
2		
3		
4		
5		
6		
7		
8		

20. Product Information Leaflet (PIL), Consumer Information Leaflet, Promotional materials, Label & Packaging materials ((Please "√ ")		Yes		No	
Original PIL	Product name				
	Ingredient list				
	Indication				
	Contra indications				
	Warnings / Precautions				
	Dose				
	Side effects				
	Storage conditions				
	Address of the manufacturer				
	Any other				
Original Packaging		Primary Pack		Secondary Pack	
		Yes	No	Yes	No
Original Labeling	Ingredient List				
	Storage				
	Heath Claims				
	Manufacturer Name & Address				
	Manufacturing Date				
	Expiry Date				
	Batch No				
Original Promotional materials					
Are there any visual graphics on the product / PIL					
If Yes, describe					

Schedule	I	IIA	IIB
Recommendation of the Pharmacist			
Date	Signature		

Expert Comment

1. Application Number:
2. Name of the applicant:
3. Date of the submission of the application to the expert:
4. Date taken for evaluation:
5. Expert's Comment:

6. Any other comment:

Recommendation:

Name:.....

Designation:.....

Signature:.....

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Approved by CEO