

Borderline Product Submission Form

1. Name of the Borderline Product					
Brand Name					
Stand Ivame					
Authorization letter addressed to CEO / NMRA by the Manufacturer / Distributer	(Original)				
Copy of Sample Import License (Please "√")					
Copy of Whole Sale License (Please "√")					
Registration status: (Please "√")	New	RR	}		
Have already submitted a dossier to other regulatory body in Sri Lanka	Yes/No I		'Yes" mentioned the details		
Status of the applicant (Please " $$ ")	Manufacturer	Imp	orter		
Route of administration:		Dosage form (If applicable only)			
Type of product: (Please "√")	Medicine and Food	Medicine and Medic Device		Medicine and Cosmetic	
2. Details of the Marketing Authorizatio	n holder (Applicant) in Sri Lanka			
Name of the applicant	(, iii on Danka			
Address of the applicant					
.,					
Telephone no.					
Email / web					
Note: Overseas manufactures should for	ward their application	on only through a	local agent in	Sri Lanka	
			7,500		
3. Details of the Manufacturer (Please "	√" where needed)				
Name	· ····································				
Actual manufacturer Contract m	Contract manufacturer		Other		
Address of the Actual Manufacturing Site		Any other		•	
Product is registered and marketed in the	Registered	address			
The title			Marketed		



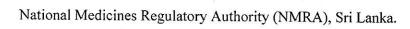
country of manufacture			
Classification in country of manufactor	ure		
Borderline Product			
Medical Device			
Health supplement			
Listed product			
Cosmetic Product			
Traditional Medicines			
Other			
If it is a Device			
D. di	If Yes	Details	
Does this product require dedicated instrumentation?	II I es	Details	***************************************
instrumentation?			
Availability of User Manual	Yes		No
Availability of Oser Maildar	103		1.0
Justification for not submitting		, , , , , , , , , , , , , , , , , , , ,	
	1		
4. Please provide documents, if regis	tered or mark	eted in the following cou	ntries
4. I lease provide documents, if regio			
Country	Product Classification		
	-		
i. Australia ii. Canada			
v. Japan v. New Zealand			
vi. Singapore vii. UK	-	- Alberton	
viii. USA			
ix. Malaysia			-
Tri . 1 1			
xi. India			
Justification for not submitting			
Justification for not submitting			
		20	

5. Please provide the following infor	rmation on fir	nished product	
5.1 Certificate of Pharmaceutical Pro-	oduct (COPP)	
5.2 Copy of Certificate of Free Sale	(CFS) (Appli	cable if COPP is not avai	ilable)
5.3 Certificate of Good Manufacturi	ng Practice (GMP) / ISO Certificate	
Justification for not submitting	0-1		
Justification for not outside.			
5.4 Approved Master formula is	sued by the N	IMRA when classifying	
5.4.1 Manufacturing formula with		men viaconi, mg	
5.4.2 Validated testing procedures		product	
J.T.Z Validated testing procedures		r	



5.4.3 Validation report	
5.4.4 Manufacturing process or Flow diagram	
Justification for not submitting	

5.5 Please provide the Certificat Please "√" the following de	te of Analysis (COA) and Stattails accordingly	pility Report for finished	d product	
	COA	Stal	Stability Report	
Appearance			omity Report	
Chemical Assay for active ingred	dients			
Limits for heavy metals				
Limits for microbial contaminati	on			
Disintegration test			**	
Any other specific test				
*Complete real time stability dat the product registration. Failure of documents are submitted; the reg cannot be produced upon renewal Justification for not submitting	on submission will cause the principle of the product will be	product to be guenonded	modil Alexander	
Justification for not submitting				
6. Please provide efficacy data if	available			
Published reports				
Detail Clinical trial report for the	product			
	product		*	
7 .Composition per dosage form				
Each Tablet/ Capsule/ 5ml/) contains:			
Name of the ingredient	B			
reame of the higherient	Botanical name (if	Amount	Function	
i.	available)	Unit: g/IU, etc		
ii.				
iii.				
iv.				
v.				
vi.				
vii.				
viii.				
ix.				
X.				
xi.				
Xii.				
Xiii.				
xiv.				
XV.				
421.			11.88%	





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xxii.					
xxiii.					
xxiv.					
XXV.		*			
Justification for not submitting		•			
8 .Instrument with standard acc	essories and	d spare parts (If a	pplicable)		
Name of the accessory / spare p	oart	Catalogue nu		Function	
6		,	- Anna Anna - A		
				-	
					,
Justification for not submitting:					
9.Please provide the following	documents	9			
9.1 PIL	- K- 4000000				
9.2 Packaging materials (prima	ry and sacar	adomi) / A mt riconl			
9.3 Promotional materials	ly allu secol	idary) / Art work			
Justification for not submitting					•
Justification for not submitting					4
Declaration					
Deciaration					
I'm responsible for the safety, q the use of this borderline product	uality & eff t.	ectiveness of the	e product and a	ny possible hazardo	us effects caused by
I declare that the particulars give are authentic or true copies.	n in this ap	plication (page1-	4) are true and	I that the supporting	documents enclosed
Signature:					
Name:					
Designation:					
Date:	Approved	by Director Gen	eral (National	Medicines Regulator	ry Authority)