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National Medicines Regulatory Authority, Sri Lanka

Checklist for	Accepting	Sample !	Import	License A	pplication	of Medicine.

(I, II, III, IV,	V : Should be filled by	y the regulatory	officer of the applicant.)

- I. Generic Name of the Product:
- II. Brand Name:
- III. Name and address of the Manufacturer:
- IV. Name and address of the Applicant:
- V. Date of Submission:

	Document	Page	Availability ²	Remarks
		number¹		
1.	Schedule (XI) form			
	- Original signature			•
	- Actual manufacturing site address			
2.	Copy of company profile approval letter			
3.	Letter of authorization from the manufacturer			
4.	Price details	:		
5.	Previous registration certificate (if applicable)	•		
	(Site transfer / Agency transfer / Existing product	₽ u		
6.	Ageny transfer letter (if applicable)			
7.	MEC approval letter for new molecular entities (if			
	applicable)		: 	
8.	Other	:		

- 1. Should be filled by the regulatory officer of the applicant.
- 2. Should be filled by the accepting officer of the NMRA.

••••••
Signature, Name and Designation of the accepting officer.
Date:

Number of valid registrations:

Number of expired registrations within last five years.

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