Evaluation form-drug registration application
Pharmaceutical documentation

Application number :

Date of submission of the application:

Date taken to evaluation :

Name of the evaluator :

A	**History of the quality failure**		
	Product withdrawal/batch withdrawal with this manufacturer	Yes	No √
	If yes attach report		

B	**Application type**			
			Check	
	1. New chemical entity (NCE)		Desc approval	
	2. New salt or ester of an existing drug		Desc approval	
	3. New generic product(NGP)		-	
	4. New combination product(NCP)		Desc approval	
	5. New dosage form of an existing drug		Desc approval	
	6. New strength		Desc approval	
	7. Vaccine		Desc approval/expert comment	
	8. Blood product		Desc approval/expert comment	
	9. Bio-tech innovator product		Desc approval	
	10. Bio-similar product		Desc approval/conformity to the guildlines	

C	**Availability of office document**		
	1. Approval letter of the manufacturer		
	2. Sample importation license		
	3. Wholesale license		
	4. Form a- schedule iv		
	5. Form b- schedule iv		

D……
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1	Generic name	
2	Trade name	
	Whether the trade name is already registered	
	If yes, to change the brand name	
3	Dosage form	

4	Strength	

5	**Type of manufacturer**	
	1. Local	2. Foreign

6	**Foreign manufacturer**			
	Actual manufacturer √	License holder	Contract manufacturer	Distributor
	1. Is the applicant is authentic to submit application of this manufacturer			
	2. Is this manufacturing/manufacturer plant is approved? (check the address of the manufacturing site in approval letter of the company profile)		Yes	Attached

7	**Regulatory situation(licensing status) in other countries**	
	List other countries where the product is registered and currently marketed	

8	**Local manufacturer**		
	1. Formulation approval		
	2. GMP approval for the product		

9	**Certificate of pharmaceutical products(COPP)**		
	1. Original		
	2. Addressed to Sri Lanka		
	3. Valid at the point of submission		
	4. Signed by the designated person		
	5. Compare the composition		
	6. Product registered and currently marketed		
	7. Product registered and marketing in the country of manufacturing but not currently marketed		
	8. Product not registered		
Comments:			

10	**Packaging**			
	Pack type	Primary pack	Secondary pack	
	Pack size 5ml	Primary pack	Secondary pack	
	Whether the secondary package include any other (e.g.; dropper or any other measuring device, syringe, solvent pack etc.)specify		No	
	Comments:			

11	**Composition of the product**		
	All ingredients, active and inactive are listed by their official or approved name and include the exact quantities as per unit dose or if it is not practical, as percentage of the total formulation	Yes	No
	Dosage form and strength		
	Description of the product		
	Manufacturing formula		
	A. Master formula		
	B. Specification and test methods of all ingredients		
	Comments:		
	Method of manufacture		
	Comments:		
	Validation of important manufacturing operations		
	A. Reports available-sterilization		
	B. Reports available-filling		

12	**Quality specification**		
	Finished products	Pharmacopoeia specify	In house

13	**Active pharmaceutical ingredients(API's)**		
	API quality standard ……BP edition…… …..EP edition…….. ….USP edition……. ……IP edition……. ……Other specification or additional		
	Certificate of analysis attached	Yes	
	Name, country of API manufacturer is stated		
	A technical file including the synthesis route, the site(s) of manufacture, the potential by products and the potential impurities) is submitted		
	API manufacturer GMP compliance has been certified		
Comments:			

14	**Finished products quality specification and test methods**		
	……BP edition…… ……USP edition……. ……Other (*)……. .		
	Attach copy of finished products quality specification		
	Limits in % for the assay in active ingredient ……95-105% ……90-110% …..Other……		
	In case of in house s, test method validation reports are provided		
	The specification covers,		
	A. Identification of active=8ve ingredients,		
	B. Quantitative determination of the of active ingredient(s) and preservatives		
	C. Tests for impurities		
	D. Test for degradation products		
	E. Dissolution		
	Attach a certificate of analysis for batch release		

Comments:

15 evaluation of analytical validation data		
Item	Data provided by the applicant	Acceptable or not? Give comments separately
Is a chromatogram or similar provided		
Specificity		
Linearity		
Range		
Accuracy		
Precision		
Other comments:		

16	**Stability**		
	Stability testing data available	Yes	No
	Claimed shelf life		
	Recommended storage condition		
	Types of study		Accelerated
	Satisfactory with respect to conditions of study		
	Temperature		
	Relative humidity		
	Intervals of testing		
	Period of testing		
	Type of container		
Other comments:			

17	**Data sheets giving the following information**		
	A. Pharmacology		

	• Pharmacological action		
	• Mechanism of action		
	• Relevant pharmacokinetic data		
	• Bio-equivalence/bio-availability data (when necessary)		
	B. Clinical information		
	• Indications		
	• Contra indications		
	• Precautions		
	• Warnings		
	• Adverse effects		
	• Drug interactions		
	• Dosage regime		
	• Average dose and dose range for adults and children		
	• Dosing intervals		
	• Average duration of treatment		
	• Dosage in special situations (e.g. Renal, hepatic and cardiac insufficiency)		
	Over dosage: brief clinical description of symptoms/treatment of over dosage		
Comments:			

18	**Comparison of PIL with data sheet**

19	**Comments on the sample provided**
	Two finished product samples enclosed

20	**Bio-availability**		
	Demonstrated by in vivo bio-equivalence study	Yes	No
	Reference product(name & company)		
	No of volunteers		
	Performed year		
	Country of study		
Comments:			

21	**Label**		
	Attached a copy		
	Comply with regulations		
	Compared with the sample provided		
Comments:			

Recommendation:

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Date evaluator's signature