ANNEXURE - I

Product Complaint and Suspected Adverse Effect / Reaction Reporting Form

Choose appropriate Product Category

☐ Medical Device	☐ Cosmetic Product	☐ Drug Product	☐ Preservative	☐ Biocide	☐ Others

☐ New	☐ Follow-up If it's a follow-up, pl specify previous case number:

Complaint No. & Date (To be filled by Schulke India Quality Representative)	:	Click or tap here to enter text.

Reporter & Customer Information		
Reporters Name	:	Click or tap here to enter text.
Customer Name	:	Click or tap here to enter text.
Customer address	:	Click or tap here to enter text.
Customer Phone & email	:	Click or tap here to enter text.

Product Information				
Product Name & Pack Size	:	Click or tap here to enter text.		
Batch Number	:	Click or tap here to enter text.		
Manufacturing & Expiry Date	:	Click or tap here to enter text.		
Do you have the Complaint Sample?	:	☐ Returned	☐ Available with the User	
		☐ Not available with the User		
Are you holding stocks of the aforesaid batch?	:	☐ Yes pl specify # of Bottles / Cans / Drums	Click or tap here to enter text.	
		☐ No		

Complaint Type			
☐ Product Quality	☐ Packaging Quality	☐ Adverse Event	☐ Other(s)

Part A: Describe the nature of the issue observed (To be filled in case of Product Quality, Packaging Quality or Other concerns)		
Click or tap here to enter text.		
Attached Complaint Evidence	☐ Yes	☐ NO

Part B: Patient information in case of Suspected Adverse Effect (AE) or Adverse Drug Reaction (ADR)		
Gender	:	Click or tap here to enter text.
Name	:	Click or tap here to enter text.
Age or Date of Birth	:	Click or tap here to enter text.
Weight & Height	:	Click or tap here to enter text.
Reason for Use	:	Click or tap here to enter text.

ANNEXURE - I

Route / Mode of Application	:	Click or tap here to enter text.
Anymore persons affected?	:	Click or tap here to enter text.
If Yes... How many?	:	Click or tap here to enter text.

Information on Suspected Adverse Effect (AE) or Adverse Drug Reaction (ADR)

Contact details of involved Physician / Pharmacist (Name / Address / e-mail / Phone / Fax)

Click or tap here to enter text.

Progress of Adverse Effect / Adverse Drug Reaction and therapy (if applicable, use attachment)	Life threatening?	Yes ☐	No ☐

Click or tap here to enter text.

Actions(s) taken	Outcome of AE or ADR	Reactions linked to Product
☐ Surgical Intervention	☐ Unknown	☐ Definitely
☐ Hospitalization	☐ Recovered	☐ Probable
☐ Prolonged hospitalization	☐ Not yet recovered	☐ Possible
☐ None of the above	☐ Irreversible damage	☐ Unlikely
	☐ Death	☐ Not assessable

Further relevant information for evaluation of the case

e.g. Underlying diseases (e.g. allergy, skin diseases), Pregnancy, Concomitant Medication, Laboratory data, Test Results (if applicable, use attachment)

Click or tap here to enter text.

Who are informed?	:	☐ Manufacturer	☐ CDSCO	☐ State FDA
Receivers details (To be filled by Schulke India Quality Representative)	:	Name	:	Click or tap here to enter text.
	:	Date	:	Click or tap here to enter text.
	:	Signature	:	

E-mail This document to	customercare.india@schuelke.com