

XYZ Pharmaceutical (Pvt) Ltd.

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RECALL ASSESSMENT FORM (ANNEXURE -I)

To _____ Recall Ref. No. -----

_____ Date: -----

Recall Information	Information by Holder of Certificate of Registration/ Distributer/Wholesaler		
Origin of Report			
1. Name of Person/ Organization reporting the problem			
2. Date of Report			
3. Name of recalling firm			
4. Physical address of recalling firm			
5. Telephone number of recalling firm			
6. Alternate number of recalling firm			
7. Email address of recalling firm			
8. Name of Quality Head/ QA Head of recalling firm			
Product Detail			
1. Name of product affected			
2. Registration number			
3. Dosage form			
4. Strength			
5. Pack size/type			
6. Batch number and expiry date			
7. Date Manufacture			
8. Date released			
9. Total quantity prior to distribution			
10. Quantity released for distribution prior to the recall			
11. Date of distribution (s)	Sr. No.	Distribution Name	Date

12. Local distribution	
13. Overseas distribution	
Name of Defect	
1. Source of problem	
2. Detail of problem	
3. Number of complaints received if any	
4. Action taken so far (if any)/Proposed action and its urgency	
5. Type of hazard/health risk and assessment of risk to the user	
6. Proposed recall classification and level of recall	
7. Other relevant information	