POLICY ON COMPLAINTS

INTRODUCTION:
…… seeks to maintain its reputation as a firm delivering high quality medicines.

The policy is designed to provide guidance on the manner in which …….shall handle complaints made against any of our products.

The objective of the policy is to ensure resolving complaints in an efficient, effective and professional manner.

SCOPE:
This policy is applicable to drug substances, drug products and medical devices manufactured and distributed by …….

POLICY DETAILS:

- All complaints received either in writing, oral, electronic or any other source shall be recorded and acknowledged. Acknowledgement to the complainant shall be sent within 1 business day.
- All incoming complaints shall be categorized either as critical or non-critical based on the extent of health risk, legal or regulatory impact and forwarded to Manufacturing site for investigation.
- Every complaint shall be investigated and efforts shall be made to identify the root cause of complaint.
- Complaint Assessment, Investigation and Corrective and preventive actions shall be carried out by trained and experienced staff with subject matter expertise.
- The investigation findings shall be shared with the complainant through Corporate Quality Assurance.
- Each complaint shall be evaluated for sterility breach (sterile products) & patient safety, need of Field Alert report (FAR)/ Potential FAR for USA market as per 21 CFR 314.81(b)(1)(i) and (ii).
- All Medical/ Technical and Medical complaints like AE and LOE complaints where ….. is the MA holder shall be assessed by ….. Drug Safety Department.
- Corrective and preventive actions shall be put in place to mitigate the risk of repetition of complaint. All complaints shall be closed in a timely manner.
- Periodic trend analysis of complaints shall be performed as part of continuous improvement.

AMENDMENT AND WAIVER:
The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not Applicable

ABBREVIATIONS:

AE	:	Adverse Event
CQA	:	Corporate Quality Assurance
LOE	:	Lack of Effect
EU	:	European Union
GMP	:	Good Manufacturing Practices
MA	:	Marketing Authorization

REFERENCES:
EU Guidelines for GMP-Eudralex: Part 1. Chapter 8: Complaints, Quality Defects and Product Recalls.