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RWANDA FDA Rwanda Food and Drugs Authority	Title: **PROCEDURE FOR ANNUAL INSPECTION PLANS FOR ALL LICENSED PHARMACEUTICAL ESTABLISHMENTS**	Revision Number	: 0
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1.0 Purpose

This Standard Operating Procedure is to:

1.1 Guide the preparation of the inspection plan to ensure that licensed pharmaceutical establishments comply with laws and regulations governing the manufacture, labeling, and handling of medical products that are commercially distributed in Rwanda.

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to all pharmaceutical manufacturing premises
2.2 Applies to all wholesale pharmacies and Retail Pharmacies

3.0 Policy

3.1 The Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning states in:
Article 3 (13) … *"premises used in the manufacture of products regulated by this Law"* and

3.2 ISO 9001:2015 Clause 7.5.3.1 states that "*Documented information required by the quality management system and by this International Standard shall be controlled".*

4.0 Definition and Abbreviation

4.1 **N/A**

5.0 Responsibility

5.1 Head of Department of food and drugs inspection and safety monitoring is responsible ensures that this SOP is correctly and consistently implemented during the inspection plan of pharmaceutical establishments.
5.2 The Division Manager of food and drugs inspection and compliance ensures staff adherence to this SOP.
5.3 Quality Assurance Analyst who is a person in charge of quality management system ensures the use of the updated version of this SOP, recalls obsolete version of this SOP and record this SOP in a master list document of the Authority.
5.4 Drugs Inspection & Compliance Analyst prepares and submits the inspection plan to the Division Manager of food and drugs inspection and compliance
5.5 Analyst and Specialist are responsible to adhere to the inspection plan of pharmaceutical establishments

6.0 Distribution

6.1 Head of Food and Drugs Inspection and Safety Monitoring
6.2 Division Manager, Food Inspections & Compliance Division
6.3 Drugs Inspection & Compliance Analyst
6.4 Quality Assurance Analyst
6.5 Specialist/Analyst
6.6 A QMS shared folder on Rwanda FDA head office server on the following link: (\\rwandafdaserver\qms\sops\)
6.7 Hard copies to staff that have no access to the Rwanda FDA server.

7.0 Safety Precautions

Not applicable to this SOP

8.0 Materials and equipment

8.1 Database of licensed regulated establishments

9.0 Procedure

9.**1** The Division Manager of Food and Drugs Inspection and compliance shall appoint the team and designate the team leader with the adequate competency as per the inspection to be undertaken The appointed team under the coordination of the Team Leader shall examine the product safety/quality risks factors from production environment, processes, products composition and the history of products to compliance with existing quality and safety management.

9.2 The appointed team shall select method of inspection and priorities establishments to inspect as the results of the analysis of the risks factors of product safety/ quality.

9.3 The appointed team shall submit the risk categories of establishments depending on their products and prioritization of establishments for inspection to the division Manager of Food and drugs Inspection and compliance for review.

9.4 The reviewed risk assessment based inspection plan shall be submitted to The Head food and drugs inspection and safety monitoring department for approval.

9. 5 After the approval of the plan, the inspectorate shall officially inform the manufacturer on the proposed date(s) of the inspection

9.6 The inspection plan shall be implemented as scheduled**.**

9.7 All used forms, various meeting minutes, records of methodology used for the risk categorization of establishments, proof for periodic review of the inspection plan shall be maintained in appropriate files.

10.0 References

10.1 The Rwanda FDA Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning.

10.2 Rwanda FDA Suitability and Licensing of Premises Regulations and Guidelines.

11.0 Appendices

N/A

12.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16 Jul 2021	0	Rwanda FDA Staff	First Issue

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