	Department	Food and Drugs Inspection and safety monitoring
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RWANDA FDA Rwanda Food and Drugs Authority	Title: PROCEDURE FOR ANNUAL INSPECTION PLANS FOR ALL LICENSED PHARMACEUTICAL ESTABLISHMENTS	

1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to 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 applies to:

2.1 Pharmaceutical manufacturing premises.
2.2 Wholesale pharmacies and Retail Pharmacies

3.0 Responsibility

3.1 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.
3.2 The Division Manager of food and drugs inspection and compliance ensures staff adherence to this SOP.
3.3 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.
3.4 Drugs Inspection & Compliance Analyst prepares and submits the inspection plan to the Division Manager of food and drugs inspection and compliance
3.5 Analyst and Specialist are responsible to adhere to the inspection plan of pharmaceutical establishments

4.0 Distribution

4.1 Head of Department of food and drugs Inspection and safety monitoring
4.2 Division Manager Food and drugs Inspection and Compliance
4.3 Drugs Inspection & Compliance Analyst
~~4.3~~4.4 Quality Assurance Analyst
~~4.4~~4.5 Specialist/Analyst

	Author	Authorized by			Approved by
Title			Division manager drug and food inspection and compliance	Head of department of food and drugs Inspection and safety monitoring	Director General
Signature & Date					

5.0 Procedure

5.1 Each local licensed pharmaceutical establishment will be inspected by the Authority at least once a year.

5.2 In the first month of each fiscal year, the Drugs Inspections & Compliance Analyst updates the database of licensed pharmaceutical establishments and then prepares an annual inspection plan covering all licensed pharmaceutical establishments with detailed schedule of their inspection.

5.3 The prepared annual inspection plan is sent to the Division Manager of Food and Drugs Inspection and Compliance for verification and then submitted to the Head of Department of Food and Drugs Inspection and Safety Monitoring for approval. The annual inspection plan of licensed pharmaceutical establishments shall be approved not later than the last day of the first month of the fiscal year/financial year.

5.4 The approved annual inspection plan is shared with food and drugs inspection and compliance division for their preparedness and implementation.

6.0 Records

6.1 Signed annual inspection plan shall be maintained at the registry for a period of five years and then disposed of by tearing/burning/shredding or any other appropriate method

End of Document

	Author	Authorized by			Approved by
Title			Division manager drug and food inspection and compliance	Head of department of food and drugs Inspection and safety monitoring	Director General
Signature & Date					