


Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	Food and Drugs Inspection and Compliance Division
Document Type: Checklist		Doc. No : FDISM/FDIC/CKL/038
 <p>RWANDA FDA Rwanda Food and Drugs Authority</p>	Title: GOOD MANUFACTURING PRACTICES (GMP) INSPECTION APPLICATION REQUIREMENTS FOR FOOD PRODUCTS	Revision Number : 1
		Revision Date: : 30/10/2022
		Effective Date : 30/12/2022
		Review Due Date : 29/12/2025
		Ref Doc. : FDISM/FDIC/GDL/004

No	Documents	Observation
1	Filled and signed application form	
2	Proof of payment of prescribed fees	
3	Food safety prerequisites manual(FSPM)	
4	License of premises for food product manufacturing	
5	List of all the products manufactured on site	
6	A copy of any warning letter or equivalent Regulatory action issued by any authority to which the site provides or has applied to provide the product.	
7	Corrective action (CA) related to the GMP inspection report observations/non-compliances if any.	
8	GMP inspection report issued by other competent authorities, if any.	
9	Current GMP Certificate/ISO 22000/HACCP/FSSC 22000/BRC if any.	
10	Product description including brief description of product validated formulation, product testing results and stability study report.	
11	Self-inspection report.	
12	Quality Manual/Laboratory Manual or equivalent.	
13	The most recent batch records.	
14	A list of any recalls or any Market complaints register in the last three years.	
15	Contract or agreement between manufacturer and the outsourced testing laboratory (List of Subcontractor).	