Session 3:

Preparation of a Product Dossier for Condom Prequalification

World Health Organization

UNFPA

PATH
A catalyst for global health

Session Objectives

- Give overview of all necessary components of a Product Dossier
- Identify key reference documents
- Practice strengthening a Product Dossier

Purpose of Product Dossier

- Provide UNFPA with a description of the manufacturer's condom specifications, including raw materials, manufacturing processes, testing, and quality assurance (QA) systems

Purpose of Product Dossier
(continued)

- Enables assessment of:

  -Whether, through documentation, the product meets requirements of *Model Specification*

  -Whether a site inspection should be scheduled

Key Reference Documents

- Prequalification Scheme for Male Latex Condoms – Annex 2, page 27
- Male Latex Condom Specifications and Guidelines for Condom Procurement 2003
- *ISO 4074:2002 – Natural Latex Rubber Condoms: Requirements and Test Methods*
- *ISO 2859-1 – Sampling Procedures and Tables for Inspection by Attributes*

Introduction

- A Product Dossier must be submitted to UNFPA as part of the prequalification process
- The information in the Dossier should come from existing documents
- The information must be submitted in English
- Pages should be numbered

Cover Page

- The cover page should include:
  - –“Product Dossier – [Company Name]”
  - –[Company address, contact telephone number, and email]
  - –[Date of preparation]
  - –“Strictly Confidential”

Table of Contents

- Key headings:
  - Characteristics of the products (design and marketing)
  - Raw materials
  - Sites of manufacture
  - Manufacturing process
  - Specifications of the products (compare with *Model Specification*)
  - Test procedures (evidence of conformity)
  - Stability Data
  - Attachments (if any)

Characteristics of Product
(Design and Marketing)

1. Details of the product
2. Product sample
3. Local, country, regional, and regulatory approvals for the product

Raw Materials

1. List all raw materials that are currently used in the manufacture of condom product

2. For all chemicals used, provide chemical name, brand name, and function

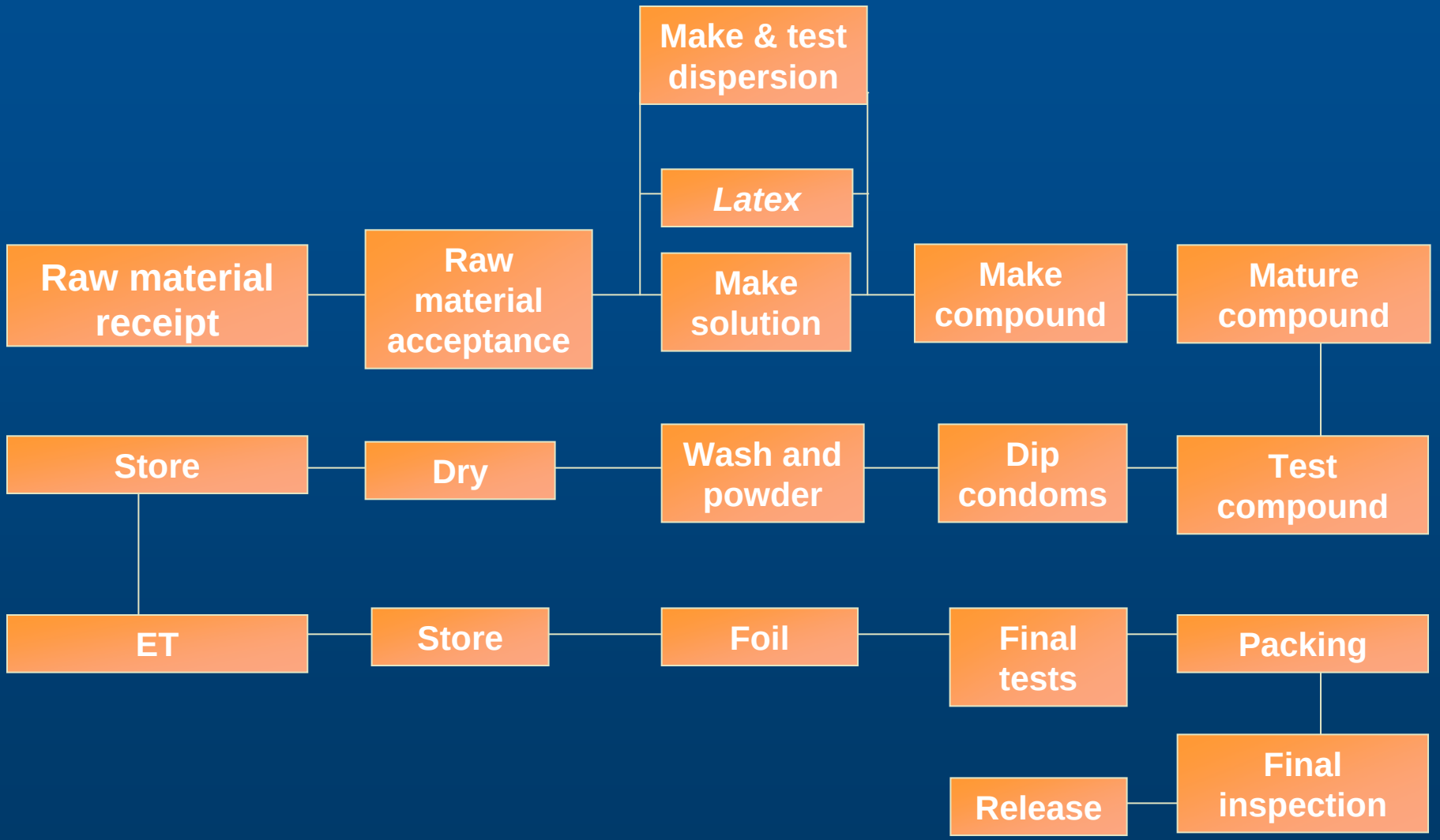
Sites of Manufacture

1. Provide complete contact information for each site at which *ANY* aspect of manufacturing occurs
2. Describe the nature of activities performed at each site

Manufacturing Process

1. Provide a flow diagram of the complete manufacturing process, giving relevant information for each stage
2. Provide a written description of the manufacturing process and packaging, and scale of production

Typical flowchart



Manufacturing Process

Provide:

3. Risk management plan for product as required by ISO 13485
4. Sampling plan showing where, when, how samples are taken
5. Test and acceptance criteria performed at critical steps of manufacturing process

Can reference the SMF where appropriate

Manufacturing Process

6. Final release data of one (1) manufacturing lot. Should contain:
    - Lot analytical data
    - Certificates of analysis
    - Lot production records including lot release test results
    - Report on unusual findings, modifications or changes with appropriate rationale
    - Conclusions

Specification of the Products

1. Include the specification for the finished product using the Model Specification as a guide
2. Highlight any deviations from the Model Specification

Evidence of Conformity

1. Supply documentary evidence that the product conforms to the current Model Specification
    - Chapter 2, clause 3.1 – General Requirements

Stability Data

1. Must present data supporting shelf life of product
2. Should include data demonstrating compliance with minimum stability requirements of *ISO 4074:2002,* Section 7.2
3. Should include real time data from stability studies conducted at 30°C (range 28°C-35°C) per *ISO 4074:2002,* Section 7.3

Stability Data

4. If results of real time studies are not available prior to prequalification, studies should be underway.
5. Pending the outcome of the real-time studies, manufacturers may provide data on either:
   - Accelerated stability studies at elevated temperatures; or
   - Their own established and validated procedures for establishing shelf-life estimates

Attachments

1. Ensure that a list of attachments is included as a first page of this section
2. Ensure that each attachment is numbered as per your list so that it may be readily identified

Questions?

Practice Strengthening a Product Dossier

Small Group Exercise

Instructions:

- Work in small groups
- Each group reviews section of Product Dossier
- For each section, note problems and suggestions for improving the adequacy of the Product Dossier

PRODUCT DOSSIER

CASE STUDY EXERCISE

SIEVE CONDOMS INC

NEW ZEALAND

www.sieve.nz

Contents

1. Characteristics of Product

Details of the product

1. 48 mm
2. 53 mm
3. 57 mm

Local, country, regional, and regulatory approvals for the product

The products are registered and for sale in the following countries:

- New Zealand
- Fiji
- Tuvalu
- Tonga

The products have been withdrawn from the market in the following country:

- Kiribati

An application for marketing authorization is currently pending in:

- Western Samoa

2. Raw Materials

Chemical name	Brand	Function
Sulphur	BASF	Compounding
Antioxidant 1	Nonoxo	Compounding
Antioxidant 2	Great Wall	Compounding
Alkali	Chemo	Stripping bath
Accelerator	Hivulc	Compounding
Talc	Desorba	Powdering
Sodium Chloride	Saxa	ET electolyte
Toluene	Shell	Swelling test

Supplier(s)

Latex is purchased from Mitsui Trading Co.

3. Sites of Manufacture

The only manufacturing site is at our main address, listed on the front cover.

4. Manufacturing Process

The process consists of the following steps:

1. Compounding of latex with vulcanizing chemicals
2. Dipping of formers in the latex
3. Drying of formers
4. Dipping of formers in the latex
5. Drying of formers
6. Rolling of bead
7. Vulcanization
8. Stripping of condoms from formers
9. Powdering and washing
10. Drying
11. Electronic testing
12. Foiling
13. Final packing

Process Stage	Test Type	Sample Size and Frequency	Specification	Accept/Reject or Rework Criteria
Dipping	Mass	5 per 2 hrs	1.62 to 1.65	Ac 1 Re 2
After processng	Mass Visual Holes Inflation	5 per 2 hrs 50 per 2 hrs 50 per 2 hrs 50 per 2 hrs	1.55 to 1.58 See list ISO 4074 Min V 32 L Min P 1.8 kPa	Ac 1 Re 2 Ac 2 Rework 3 Ac 1 Reject 3 Ac 3 Reject 4
After ET	Holes	50 per 2 hrs per machine	ISO 4074	Ac 0 Rework 1
After foiling	Holes Pack seal Lub quantity	50 per 2 hrs per machine 30 per 2 hrs per machine 20 per 2 hrs per machine	ISO 4074 ISO 4074 200 to 600 mg	Ac 1 Rework 2 Ac 1 Reject 2 Ac 1 Reject 2
Final packing	None			
Release test	Full ISO	ISO	ISO	ISO

Product test report

A test report for one batch is included in the attachments.

Risk Management

A copy of the risk management study is in the attachments.

5. Control of the Products (specifications)

The products comply completely with the WHO requirements.

6. Test procedures

Data showing compliance with the general requirements of the WHO Model Specification are given in the attachments

7. Stability Data

Shelf life information is given in the attachments

Sieve Condoms Inc
Case Study Exercise for Strengthening a Product Dossier

Problems with Product Dossier

1.

2.

3.

4.

Suggestions for Addressing Each Problem Above

1.

2.

3.

4.