Documents Under Development

• PREQUALIFICATION PROGRAMME GUIDANCE FOR CONTRACEPTIVE DEVICES: MALE LATEX CONDOMS, FEMALE CONDOMS AND INTRA-UTERINE DEVICES
• TECHNICAL SPECIFICATION FOR MALE LATEX CONDOMS
• RECOMMENDATIONS FOR CONDOM STORAGE AND SHIPPING TEMPERATURES
• GUIDANCE ON CONDUCTING POST MARKET SURVEILLANCE OF CONDOMS
• CONDOM QUALITY ASSURANCE
• SPECIFICATIONS FOR PLAIN LUBRICANTS
• TCU380A INTRAUTERINE DEVICE (IUD) SPECIFICATION, PREQUALIFICATION AND GUIDELINES FOR PROCUREMENT
• STED
Major Changes

• Separate document for guidance on prequalification programmes for contraceptive devices – covers male and female condoms, and IUDs

• STED (Summary of Technical Documentation) will replace Product Dossier and Site Master File
Technical Specification for Male Condoms

Key Changes:
Date of manufacture can be date of dipping or packaging
   Packaging must occur within six months of dipping
Biocompatibility assessments conducted on whole condom including lubricants, finishing powder and any additives
Extraction conditions for preparing samples for biocompatibility testing are specified
Definition of bioburden units corrected - cfu/condom
Visible defects now include visibly open packaging seals
Clarification of sample requirements for real time stability studies
Minimum code letter N (500) used for prequalification testing for freedom from holes
Amendments burst volume versus condom width table
Alternative package integrity test, inspection level and AQL included for condoms being shipped by air and/or sent to high altitude countries
GUIDANCE ON CONDUCTING POST MARKET SURVEILLANCE OF CONDOMS

Main focus of Guidance is conducting surveillance testing on samples recovered from the field

Key Elements Covered:

• Sampling – sample sizes and selection of tests
• Selection of laboratories for testing
• Testing and evaluation of results
• Interpretation of results
RECOMMENDATIONS FOR CONDOM STORAGE AND SHIPPING TEMPERATURES

Guidance on shipping and storing condoms
Key focus on specifying and controlling temperatures
CONDOM QUALITY ASSURANCE

Guidance on condom quality assurance

Covers the following:

• Role of standards
• Main changes introduced in the 2015 edition of ISO 4074
• Specifications and WHO/UNFPA Prequalification scheme
• Role of regulatory authorities and regulatory procedures
• Essential components of a Quality Management System
• Definition of a lot
• Lot by lot pre-shipment compliance testing
• Sampling, AQLs, monitoring quality and selecting testing laboratories
• Discussion of testing costs
• Post shipment and confirmatory testing
• Resolution of disputes
• Sampling methods
• Assessment of suppliers
Specification for Plain Lubricants

Specification for additional lubricants to be used with male and female condoms in reproductive health programmes

Based on outcome of:

- Global Consultation on Lubricants in November 2016 in Bangkok
- Follow up meeting held in conjunction the 34th ISO/TC 157 Meeting in Malaysia in September 2017

Key Elements

- Covers water based and silicone lubricants
- Lubricants shall be free from fragrances, colour, spermicides, herbal ingredients and special ingredients which claim specific pleasure enhancing properties
- Lubricants shall be compatible with condoms
- Lubricants may supplied sterile in unit dose containers as well as in bulk containers with preservatives
Key Specification Requirements Water Based Lubricants

- Osmolality shall be less than 1200 mOsm/kg
- Total glycol content shall be less than 8.3 mass fraction (%w/w)
- pH shall be in the range 5.0 to 7.0 (lubricants with a low buffering capacity that do not disturb the pH of the vagina or rectum are preferred)
- Viscosity shall be within the tolerance of ± 10 % of the value specified by the manufacturer
- The manufacturer shall be controlled below 100 CFU per gram (USP 1111). There shall be an absence of Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans and Escherichia coli
- If the lubricant is claimed to be sterile, it shall comply with a Sterility Assurance Level of $10^{-6}$
- Minimum shelf life of 3 years from the date of manufacture
- In line with ICH guideline Q1A(R2), accelerated stability studies shall be conducted at 40°C ± 2°C/75% RH ± 5% RH. Manufacturers may elect to use higher temperatures such as 50°C and 60°C providing the results can be correlated with real time shelf life estimates at 28°C to 35°C.
Key Specification Requirements For Silicone Lubricants

- Viscosity shall be within a tolerance of ± 10% of the value specified by the manufacturer. The manufacturer shall submit the method of determination of viscosity, giving details of equipment, temperature conditions, spindle speed, spindle number, shear rate.
- Lubricants shall contain a minimum of 30% polydimethylsiloxane (dimethicone) with a viscosity of 5 cps and above (mixtures of polydimethylsiloxanes with different viscosities are permitted).
- The manufacturer shall be controlled below 100 CFU per gram (USP 1111). There shall be an absence of Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans and Escherichia coli.
- If the lubricant is claimed to be sterile, it shall comply with a Sterility Assurance Level of $10^{-6}$.
- Minimum shelf life of 3 years from the date of manufacture.
- In line with ICH guideline Q1A(R2), accelerated studies shall be conducted at 40°C ± 2°C/75% RH ± 5% RH. Manufacturers may elect to use higher temperatures such as 50°C and 60°C providing the results can be correlated with real time shelf life estimates at 28°C to 35°C.
Other Requirements

- Packaging
- Labelling
- Testing – manufacturers shall submit certificates of analysis for each lot
- Certificates to include:
  - Visual inspection
  - pH
  - Viscosity
  - Bioburden
  - Visual inspection of packaging and labelling
The United Nations reproductive health and rights agency

Ensuring rights and choices for all

UNFPA