Condom Storage conditions and Stability Studies

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Condom Storage conditions and Stability Studies

- Factors affecting condom stability
- Condom storage conditions
- Stability studies as per WHO/UNFPA specification and ISO 4074: 2015
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Factors affecting condom stability

a) **environmental:**
- Light, especially UV light
- Heat
- Air – oxygen
- Mechanical damage
- Microbial contamination

b) **Formulation and process:**
- Accelerators and residual accelerators
- Antioxidant and residual antioxidant levels
- Extent of vulcanisation – cross linking
- Maximum storage period in unfoiled condition
- Type of packing materials and efficiency of sealing process
- Added substances
Factors affecting condom stability

c) Storage conditions:

• WIP storage containers
• Storage temperatures
• Duration of storage
• Storage of finished products – temperature and duration

d) Shipping, clearance, transport and distribution:

• Temperatures and duration
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Requirements of storage conditions:

Storage at mean 30 °C (range 28 °C to 35 °C)

Compliance:
• Mean temperature – temperature mapping
• Moving monthly mean temperatures, worst case scenario
• Additional controls when external warehouses are engaged
• Storage in port, handling and distribution stages
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Requirement:

As per WHO/UNFPA technical specification and ISO 4074: 2015

a) Minimum stability requirements

b) Accelerated stability studies

c) Real time stability studies
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Maximum storage period in unfoiled condition

First step regarding shelf-life and stability studies

ISO 4074: Maximum of 2 years from the date of dipping – proposal for revision

WHO/UNFPA specification: maximum of 6 months from date of dipping

Manufacturers SOP to be substantiated by validation protocol to confirm compliance with the requirements of Burst properties and Freedom from holes.
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Maximum storage period in unfoiled condition

First step regarding shelf –life and stability studies

- To be established for product type families, substantiated by justification
- 3 production batches, validation batches in case of new product
- Sample size – Annex B of ISO 4074
- Moving bench mark to save time
- Retrospective validation
- Review / re-validation
Stability studies:

- Samples from 3 production lots
- Sample size as per Annex B of ISO 4074
- Minimum stability, accelerated stability studies and real time stability studies
- Recording temperature in case of all these studies and conditions
- Additional samples
- Freedom from holes, burst properties, package seal integrity and any obvious visual damage/changes
- Product type matrix – texture, colour, flavour
Stability studies:

• Monitor mean and standard deviations of burst properties

• 95% lower confidence limit value of mean burst properties – usefulness

• Pick up early warning signals

• Revalidation – validity of data
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Stability studies:

- **On-going stability studies**
- **One batch per year, limited sampling points**
- **Compare data with original stability studies, especially the mean and standard deviations**
Thank you