World Health Organization/United Nations Population Fund Recommendations for condom storage and shipping

DRAFT FOR COMMENTS

Please send your comments to Dr Sabine Kopp, Team Lead, Norms and Standards for Pharmaceuticals, Technical Standards and Specifications (kopps@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) before 20 August 2020.

Our working documents are sent out electronically and they will also be placed on the WHO Medicines website http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/ for comments under the “Current projects” link.

If you wish to receive all our draft guidelines, please send your email address to joncesi@who.int and your name will be added to our electronic mailing list.
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Background

The report of the Fifty-fourth meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in 2019 (1) stated the following:

As agreed at the ECSPP meeting in October 2018, the United Nations Population Fund (UNFPA) and WHO have separated out different aspects of the current procedure for contraceptive devices and condoms and are developing seven different documents:

- prequalification programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices;
- technical specifications for male latex condoms;
- specifications for plain lubricants;
- condom quality assurance;
- guidance on testing of male latex condoms;
- recommendations for condom storage and shipping temperatures; and
- guidance on conducting post-market surveillance of condoms.

All seven documents were restructured and revised in the first half of 2019, then sent to the EAP and put out for public consultation in July 2019. The comments received were reviewed by a group of specialists in October 2019, prior to being presented to the ECSPP. At UNFPA’s request, the ECSPP focused on the first three documents (on UNFPA’s Prequalification Programme guidance, condom quality assurance and specifications for plain lubricants), noting that all comments have been addressed. It suggested some further minor revisions, including recommending changes to clarify that, while the specifications for plain lubricants are principally targeted at procurement agencies, they may also be used by regulators for public procurement. The next steps for the remaining four documents include incorporating comments from the latest consultations and then bringing them back to the ECSPP for possible adoption at its next meeting in 2020.
1. **During shipment**

Store condoms in dry conditions away from direct sources of heat and sunlight.

The average mean kinetic temperature\(^1\) (MKT) during shipment should not exceed 30 °C. Peak temperatures should not exceed 50 °C\(^2\). The use of data loggers to monitor all shipments that originate, terminate or transit hot climatic zones is recommended. Ideally, data loggers can calculate the mean kinetic temperature either automatically or by using software supplied with the data loggers after data has been downloaded.

2. **Warehouse storage**

Store in well ventilated, dry conditions away from direct sources of heat, including sunlight.

Long-term (i.e. one month to a year) average storage temperature should be less than 30 °C. Short-term (i.e. up to one month) temperature excursions should not exceed 40 °C. The recommended limit for short term exposure is cumulative over the total period of storage.

Condom factories prequalified by UNFPA will have provided evidence to verify the claimed shelf-life of the product. The shelf-life is determined by a real-time study, conducted at a specific temperature (30 +5/-2 °C) because this is the MKT of the most extreme climate in climatic zones III and IV\(^3\). Research has demonstrated that properly packaged good-quality condoms stored at average temperatures in tropical climates do not deteriorate during storage. More information about the recommendations for storage and shipment, and the rationale for choosing 30 +5/-2 °C as the storage temperature for stability studies, is given in the Technical Basis Paper of the WHO/UNFPA *technical specifications for male latex condoms* (3).

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\(^1\) Temperatures during shipping can be monitored using data loggers. Most modern data loggers can automatically calculate and print out the mean kinetic temperature (MKT) (in some cases, data has to be downloaded and analysed using provided software).

\(^2\) Brief, short term temperature excursions up to 50 °C have limited impact on MKT. If, during shipping, the MKT exceeds 30 °C and/or peak temperatures exceed 50 °C, a risk assessment should be conducted to assess whether or not the properties of the condoms in the consignment have been compromised. Random sampling and testing of condoms for burst properties is recommended to support the risk assessment.

\(^3\) More details on the climatic zones can be found in *WHO Stability testing of active pharmaceutical ingredients and finished pharmaceutical products* (5)
Since the shelf-life of the condoms will have been determined at $30 + 5/-2$ °C, air-conditioned storage is not necessary but it would be an advantage in hot climates, if available. In hot climates, it is important that condoms are stored in a well-ventilated environment away from direct sunlight and other sources of heat in order to minimize the exposure of the condoms to high temperatures. Similar precautions should be taken during transportation and delivery. In general, the storage temperature should be as low as can practically be achieved. Condoms stored outdoors in shipping containers are particularly vulnerable as the temperatures inside containers can be substantially above ambient temperatures resulting in faster deterioration.

Storage time in shipping containers should be minimized. The condoms are sealed in individual foil packages which are themselves packed in cardboard. The cardboard storage containers are vulnerable to moisture and should be stored in a dry storeroom away from walls and placed on pallets to protect against rising damp. Ideally, cartons should be stored at least 10 cm off the floor, 30 cm away from the walls and stacked no more than 2.4 metres high. It should be ensured that the floor of the storage area is paved with concrete and the walls and floor should not get damp due to seepage of water or rain water condensate. The ambient temperature in the warehouse should be recorded.

Condoms are fully protected by the individual foil package. However, cosmetic damage to the foil and damage to the outer packaging can make the product appear damaged and therefore less acceptable to the user. Contaminants of any sort (e.g. powders or liquids) should be avoided.

Condoms should be left in their original cartons and inner boxes until needed for distribution. The cartons should be positioned so that the lot number and expiry date are visible. The cartons should be identified and their locations recorded to ensure that specific lots can be located. Lots should be released on a first expiry—first out basis (FEFO).

Recalled, damaged or expired condoms should be kept separately and clearly segregated. The disposal of such condoms should be in accordance with local procedures for the disposal of damaged medical devices.
References


Further reading