



The European Agency for the Evaluation of Medicinal Products  
*Human Medicines Evaluation Unit*

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**COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS  
(CPMP)**

**NOTE FOR GUIDANCE ON  
MAXIMUM SHELF-LIFE FOR STERILE PRODUCTS FOR HUMAN  
USE AFTER FIRST OPENING OR FOLLOWING RECONSTITUTION**

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# MAXIMUM SHELF-LIFE FOR STERILE PRODUCTS FOR HUMAN USE AFTER FIRST OPENING OR FOLLOWING RECONSTITUTION

## GENERAL STATEMENT:

This guidance applies to all sterile products for human use, with the exception of Radiopharmaceuticals and extemporaneously prepared or modified preparations.

Because it is difficult to predict all the possible conditions under which the product will be opened, diluted, reconstituted and stored, etc., the user is responsible for maintaining the quality of the product that is administered to the patient. In order to help the user in this responsibility, the applicant should conduct appropriate studies and provide the relevant information in the User Information Texts, (e.g. SPC, Package insert, labels) following the examples given in italics below.

The applicant should also take note of the recommendations contained in the European Pharmacopoeia, with respect to storage times and conditions for specific categories of sterile products, once opened.

This guidance relates to the time between opening the product and time of administration to the patient; it takes no account of the duration of the administration process itself.

## UNPRESERVED STERILE PRODUCTS

### General

*Chemical and physical in-use stability has been demonstrated for x hours/days at y °C.*

*From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately.*

*If not used immediately, in-use storage times and conditions are the responsibility of the user.*

### Specific text for Preparations for Infusion or Injection

*Chemical and physical in-use stability has been demonstrated for x hours/days at y °C.*

*From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless reconstitution / dilution (etc) has taken place in controlled and validated aseptic conditions*

## AQUEOUS PRESERVED STERILE PRODUCTS (including antimicrobial preservatives or intrinsically self-preserving)

### NON-AQUEOUS, E.G. OILY PREPARATIONS

*Chemical and physical in use stability has been demonstrated for x hours/days at y °C.*

*From a microbiological point of view, once opened, the product may be stored for a maximum of z days at t °C. Other in-use storage times and conditions are the responsibility of the user.*

The applicant should justify the values of z and t on a case by case basis; z should not normally be greater than 28 days.