

## **Record of supplies of Extemporaneous Preparations**

Appropriately licensed specials manufacturers should be used wherever possible in preference to pharmacists preparing products extemporaneously. The specification of the product should be agreed with the supplier and should include strength, formulation and excipients. A copy of this specification should be kept and documentation should also be requested to enable verification of this specification when received.

It is good practice to keep a record of any preparations that are extemporaneously prepared within the pharmacy.

Any pharmacist choosing to compound a product in the pharmacy should record:

- The formula
- The ingredients and the quantities used
- The source of the ingredients
- The batch numbers and expiry dates of all ingredients where one exists
- The 'use by' date of the prepared product\*

If the product is in response to a prescription, the records must also include the patient's details, prescription details and the date of dispensing.

If the prepared product is made up in bulk it should be designated a reference number, which should also be recorded. This reference number should be added to all dispensing labels for supplies that are made from this particular bulk product.

The identity of all personnel involved in compounding the product and the pharmacist taking overall responsibility should also be recorded.

It is good practice to maintain the patient on a consistent formulation as dose uniformity and bioavailability may differ between suspending media and formulae.

There may be particular issues around paediatric medicines and pharmacists should take particular care if preparing these extemporaneously. Pharmacists should check to see if there are any local policies on the management of paediatric medicines.

Also refer to the resource tool on Record of supplies of Unlicensed medicinal products available at.....

For the majority of extemporaneously prepared products, there is no official guidance on the "in-use" life or "expiry date" that should be assigned; exceptions to this include mixtures preserved with chloroform (2 weeks), diluted oral mixtures (2 weeks) and diluted topical creams (2 weeks). In addition, products prepared extemporaneously according to formulae given in the British Pharmacopoeia are generally required to be recently or freshly prepared. Freshly prepared products must be made up not more than 24 hours before issue, and are often assigned a life of about 2 weeks, while recently prepared products may show deterioration if stored for longer than about 4 weeks at 15C to 25C.

Other than the examples outlined above, most "in-use" periods or shelf lives are assigned on an arbitrary basis. Any expiry date assigned must take account of the chemical, physical and microbiological stability of the preparation, and consider factors such as the method of preparation, the formulation (presence of a preservative; water content) and the method of use by the patient. It is good practice to allocate as short an "in-use" life as is practical to an extemporaneously prepared product taking into account the length of the patient's treatment course.

For the most up to date resource tool please refer to the RPSGB website:

<http://www.rpsgb.org/protectingthepublic/inspectorate/>

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For all your legal and ethical inquiries please contact the RPSGB advisory service  
on 020 7572 2308