

**Doctor of Pharmacy Department**

**PHAR 324**

PHARMACY LAW AND ETHICS

**Presentation Report**

*Title:* *Extemporaneous Pharmaceutical Preparations*

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 Extemporaneous preparations are products, which are dispensed immediately after preparation and not kept in stock. Extemporaneous preparations can be considered as unlicensed drugs where this preparation does not by law need to be concerned with quality, stability, bioavailability, efficacy and safety. As there are no published standards in the compendium, the standard depends very much on the professionalism of the pharmacist preparing the preparation. The pharmacist is referred to as the person who is skilled in the art. The uniformity of content, selection of safe excipients and stability issues form the challenges in the preparation of extemporaneous products.

 Dispensing of extemporaneous preparations of various dosage forms needs to have some ethical guidance, where this will involve the following issues:

 Extemporaneous preparations are preparation of dosage forms for particular patient consumption. There is no requirement of submission for registration with the authority so the quality of this type of preparation relies solely on the pharmacist and ethical issues on this matter need to be considered. Efforts to improve the quality of licensed and manufactured medicines are always on the agenda of pharmaceutical authorities but extemporaneously prepared products are still needed. So the pharmacist has the responsibility of ensuring that accurate and effective doses and dosage forms are made to achieve optimal drug therapy for certain groups like children and the elderly.

 Extemporaneous preparation is one facet of unlicensed drug use which can be a modification to commercially manufactured products such as the preparation of suspensions or powders from tablets or a preparation from individual raw materials where the pharmacist needs to be guided with some information from a reliable compendium. Extemporaneous preparation is popular in pediatric cases as this is to overcome the problems associated with the lack of approved medicines for children

 Among the compendiums concerned with extemporaneous to which the pharmacist ethically has to refer are: the European Pharmacopoeia (2007), which is used as an official regulation for extemporaneous preparations, the British Pharmacopoeia (BP), the United States Pharmacopeia (USP), the Australian Pharmacopoeia Formulae (APF) and Martindale (Glass and Haywood, 2006). General instructions of the extemporaneous preparation are presented in Medicinal Products for Human and Veterinary Use: Good Manufacturing Practice (Eudralex, 2007) and in PIC/S Guide to good practices for the preparation of medicinal products in healthcare establishments (Pharmaceutical Inspection Convention, 2008).

 Stability issues of extemporaneous preparations Issues affecting the stability of extemporaneous preparations may include degradation of the drug, evaporation of the vehicle, loss of uniformity, change of appearance, change of bioavailability and toxicity caused by degradation products. There should be some form of stability evidence for extemporaneous preparations. The stability of extemporaneous preparations refers to the chemical and physical characteristics of the preparation and the microbiological conditions (US Pharmacopeia, 2008).

 The shelf life of an extemporaneous preparation is predicted after an accelerated stability study has been carried out but more often extemporaneous preparations are given arbitrary shelf-lives (Costello et al., 2007). It is pertinent for a pharmacist to ensure that an extemporaneous formulation will remain within its physical, chemical and microbiological set conditions during storage for a specified time (Florence and Attwood, 2006). A short expiry period may be inconvenient for patients but a long expiry date will put the product and the user in jeopardy.

 It is clear that it is the responsibility of the pharmacist to at least perform a stability study and predict the shelf life of a commonly prepared extemporaneous preparation so that there is evidence to support the quality of the extemporaneous preparation.

STANDARDS:
 This standard is not intended to cover the reconstitution of dry powders with water or other diluents.

 Patients are entitled to expect that products extemporaneously prepared in a pharmacy are prepared accurately and are suitable for use. If you wish to be involved in extemporaneous preparation you must ensure that:

1. a product is extemporaneously prepared only when there is no product with a marketing authorization available and where you are able to prepare the product in compliance with accepted standards.
2. you and any other staff involved are competent to undertake the tasks to be performed.
3. the requisite facilities and equipment are available. Equipment must be maintained in good order to ensure that performance is unimpaired, and must be fit for the intended purpose.
4. you are satisfied as to the safety and appropriateness of the formula of the product.
5. ingredients are sourced from recognized pharmaceutical manufacturers and are of a quality accepted for use in the preparation and manufacture of pharmaceutical products. Where appropriate, relevant legislation must be complied with.
6. particular attention and care is paid to substances which may be hazardous and require special handling techniques.
7. the product is labeled with the necessary particulars, including an expiry date and any special requirements for the safe handling or storage of the product.
8. if you are undertaking large scale preparation of medicinal products, all relevant standards and guidance are adhered to.
9. Where possible, all calculations and measurements should be double checked by a second appropriately trained member of staff.
10. records are kept for a minimum of two years. The records must include:

• the formula,
• the ingredients,
• the quantities used,
• their source,
• the batch number,
• the expiry date,
• where the preparation is dispensed in response to a prescription, the patient's and prescription details and the date of dispensing,
• the personnel involved, including the identity of the pharmacist taking overall responsibility.

**References:**

Professional Standards and Guidance for the Sale and Supply of Medicines
<http://www.rpharms.com/code-of-ethics-pdfs/coepsgssmeds.pdf>

M. I. Noordin (2012). Ethics in Pharmaceutical Issues, Contemporary Issues in Bioethics, Dr. Peter A. Clark (Ed.)
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