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DOSE POWDER MANUFACTURE AND STANDARD OPERATING PROCEDURES

pHARMACEUTICS LAB REPORT BY GEORGIOS AKRITIDIS

STUDENT id;1241729468

1. **Standard Operating Procedures**

In general, a standard operating procedure (SOP), is an approved written instruction describing how a routine task should be carried out, by whom, where and when.

In pharmacy, SOP is followed to ensure that operations have been carried out in the same manner and consistently, in a situation.

In pharmaceutical lab classes we have dealt with extemporaneous preparations. These are medicines prepared for a named specific patient in response to the prescriber’s instructions. Before dispensing an extemporaneous product, we have to make sure it meets extemporaneous product standards. The product should be given a short expiry date (often only 7 days), prepared or supervised by a Pharmacist, must only be prepared against a legal prescription i.e named patient. Also, these products should have prepared using standards that comply with local and QA regional audit, released following check by any locally approved Pharmacist, have a final check and release to patient done at the same time.

The significance of following these steps in order to dispense a product properly, is related to the patient’s safety and health, and further in society’s wellbeing. In other words, it is really important, for the healthcare professional to do follow SOPs because they play a large instrumental in product’s quality and further in patient’s life. By following these approved instructions, not only they protect the society but also ensure products quality for wellness and safety, and generally reduce the errors in procedures which make up Good Manufacturing Practice (GMP).

1. **Unlicensed Medicines**

Apart from that, unlicensed medicines are prescribed when suitable ones are not in stock in order to meet the patient’s clinical needs. Two main categories distinguish unlicensed medicines, extemporaneous and specials. Extemporaneous preparations are part of specials.

Specials which are obtainable from UK commercial suppliers or from NHS pharmaceutical manufacturing units, under a Manufacturer’s Licence (Specials), issued by the MHRA, are also extemporaneously prepared as we have practised on this in pharmaceutical labs under supervision of QP. The specials products must meet the standards before they dispensed. They require a Specials Manufacturing Licence, have an expiry limited to stability evidence, are prepared by a trained person following approved Standard Operating Procedures (SOPs). Moreover, specials products are released by a person registered by MHRA ( Medicines and Healthcare Products Regulatory Agency for UK), e.g. Pharmacist or Qualified Person (QP) and are prepared using standards which must comply with MHRA inspection that are much more stringent than local/regional standards.

1. **In Practice**

On 31st of January 2018, we were asked to prepare wrapped powders (Betamethasone 0.5 mg). We followed the SOPs standards and regulations and as a result we prepared specials products.

Before starting doing the experiment we needed to make sure our calculations and dosages were right. After that, signature y two people checked our work to make sure that we follow a SOP. Then after they checked we started preparing the powder by gently mixing the ingredients and measuring out accurately the amount needed for one wrap to be made. Although the experiment asked for 8 wraps, we made 10 of them just to make sure that in case one wrap does not contain the right amount, there is one to replace it.

Then we labelled the box of the 10 wrapped powders giving it 30 days as expiry date, added the batch number and the instruction “For Stock Only”. After finishing the experiment, we had all that procedure checked again but this time form a qualified pharmacist.

1. **References**
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3. Thepsi.ie. (2018). Writing and Maintaining Standard Operating Procedures (SOPs). [online] Available at: http://www.thepsi.ie/gns/inspection-enforcement/inspections/InspectorsAdvice/SOPs.aspx [Accessed 24 Feb. 2018].
4. MPH 116 Lecture notes relating to powder processing and mixing