Standard Operating Procedure

Title	SOP-2001.02

Instructions to laboratory assignment

Author	Date
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Marie Wahlgren	
QA-Approval	Date
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Aniko Wolf	

Distribution: all students in the course pharmaceutical technology

Purpose

The purpose of this SOP is to describe the laboratory assignments in this course.

Responsibility

The teacher in pharmaceutical technology is responsible for this SOP:
The students on this course are responsible to follow these instructions:

Scope

This SOP describes the two laboratory assignments, Pre-formulation of Diclofenac and tablets of salicylic acid. These assignments are included into the course to:

- Increase the understanding of pre-formulation
- Increase the understanding of tablet formulation
- Train planning of experimental work
- Train writing and QA-reviewing of pharmaceutical quality documents
- Train evaluation of experimental results
- Train written presentation of experimental results

The course is 40 hours divided into 15-20 hours of experimental work, 3 hours of instruction and discussion and the rest is set of for planning, and reporting the work.

General

The experimental work will be performed at the department of food technology and in the tablet laboratory at the department of Chemical Engineering (KAT) and course labs in chemical center.

Before starting the explorative work you should write a plan or a production master covering what you intend to do. The plan should be written according to SOP-1002 instructions for handling and writing plans and reports and the production master in SOP-1007 Instruction for writing Production master.

Pre-formulation of Diclofenac

Diclofenac is a Non-steroid anti-inflammatory agent (NSAID) used for painkillers, migraine medicine and for treatment of rheumatoid arthritis. In this assignment you will plan and execute the determination of solubility or log P for the drug substance. The group should aim to conduct the study so that the quality of the results are good enough to include in a registration file.

The group will have to write a Plan and a Report for the work. The plan should have all of the members except one in the group as Authors. The person in the group that is not the Author should QA review the plan.

The written report should have all members of the group as Authors and the report will be given to the responsible teacher for QA-reviewing.

The Plan should be written before the laborative work is performed and the students shall on request be able to show the Plan when performing the laborative work. Prior to performing laborative work the students will have to fill in a safety evaluation for the work. This has to be controlled and accepted by the responsible teacher prior to performing the laboration.

The results from this laboration will be discussed in a seminar. During the seminar both method and results will be discussed.

The group have free hands to design how to perform this study. However to facility the work spectrophotometers are availble for the groups during the assigned time for the laboration. Diclofenac has an UV adsorption with a peak at the wavelength 276 nm. The group has also limited amounts of chemicals and these will be handed out to up on request to the group by the responsible teacher Equipment and glassware will be available. The group is recommended to investigate what equipment that is available prior to planning the study.

SOPs that are important for the practical work:

SOP-1002	Instructions for handling and writing reports and plans
SOP-1003	Handling of raw data
SOP-1005	Instructions for QA-reviewing
SOP-	Instruction for how to use a spectrophotometer

ASA-Tablet

Acetylsalicylic acid ASA is one of the most commonly used drug substances. It functions as a painkiller, but is also an anti-inflammatory agent and has shown effects for patients with cardiac diseases. You have obtained information on the standard recipe for Magnecyl but instead of making a straightforward copy you will make a 250 mg ASA tablet aimed at children above seven years old. Thus you will compare your tablet to Albyl Minor but also to the original Magnecyl tablets.

You will try to make your tablets as similar to the standard tablet as possible. You will also characterise your tablets using standard methods such as:
Hardness
Friability
Disintegration (modified method)
Uniformity of mass
Uniformity of content (UV)

You are recommended to produce around 100-150 g of tablet granulate.

You will also compare the dissolution of your tablet to Magnecyl and Albyl Minor.

Prior to the ASA-tablet laboration you will write for another group a production master according SOP 1007 detailing how the production of tablets should be performed. The person responsible for the laboration and the group that should use this master should accept the master before you are allowed to do your own laboration. The master should be filled in during the production and QA reviewed by the supervisor for final acceptance.

Background information

The following background information will help you to plan your work.

- Information about Magnecyl from Läkemedelsverket
- Aulton
- USP on immediate release tablets
- Background articles
- Flow chart for production of Magnecyl 1 million tablets
- Calibration curve for UV determination of ASA concentration

Material and equipment

Material for production:

- ASA
- Gelatin
- Magnesium hydroxide
- Talk
- Starch (potato)

Equipment:

- Varian mixer
- Con-Blender
- Tablet machine

- USP-Dissolution bath
- Spectophotometer
- Equipment for hardness measurements
- Friabilator
- Balance
- Beakers etc.

Review History

Rev 00: New
Rev 01: Added the use of production master for ASA laboration
Rev 02: Change to logP laboration