COGFORM03

# Prepare formulations for evaluation

## Overview

This standard covers the competences you need to prepare formulations in-line with the agreed plan and in accordance with approved procedures and practices.

You will be required to demonstrate that you can measure, weigh and prepare compounds and solutions in a laboratory environment in accordance with the relevant workplace procedures.

You must also be able to evaluate the hazards of materials and process to be undertaken in advance of starting work.

You will be required to accurately record the preparation protocol including any anomalies to allow the reproducibility of a future manufacturing process.

The activity is likely to be undertaken by someone in a science related work setting in any formulation sector such as pharmaceuticals, personal care, food and drink, paints or lubricants.

In these sectors a knowledge of the principles of separation technologies and the processing of solids and liquids maybe applicable. These principles are supported by the underlying scientific principles that may include the science of: colloids, interfaces, particles, materials, modelling, simulation and data management and analysis.

## Performance criteria

*You must be able to:*

P1 ensure that your work is carried out in accordance with standard operating procedures complying with health and safety, environmental and other relevant regulations and guidelines
P2 use safe practices and the appropriate personal protection equipment (PPE) when performing scientific or technical activities
P3 identify and agree the objectives of the work and produce a workplan
P4 evaluate available information on the required materials and consult with the relevant people to prepare for the preparation of the formulations
P5 identify hazards and assess risks against preparation requirements
P6 ensure that the raw materials are in specification or appropriately characterised prior to starting a formulation preparation
P7 record the origin of the raw materials and ensure traceability through the process
P8 select, calibrate and performance check the equipment to be used in the preparation of the formulations
P9 set the conditions for the preparation of the formulations and take the appropriate action to maintain them
P10 produce the formulations to specification in accordance with the agreed processes.
P11 label and store the samples in accordance with the workplace standards
P12 record accurately the preparation methods and any abnormal occurrences
P13 take corrective action in the event of abnormal occurrences, record and report them to the relevant people
P14 communicate the required information about the work done, in accordance with departmental and organisational procedures

## Knowledge and understanding

*You need to know and understand:*

K1 the health and safety regulations and guidelines relating the area in which you are working and of the materials and equipment used in the scientific or technical activities
K2 the legislation, regulations, standards and guidelines when conducting scientific or technical activities and the implications of not taking account of them when conducting the activities
K3 the principles of good practice and quality standards in the workplace including as appropriate Good Laboratory Practice (GLP), Good Clinical practice (GCP) and Good Manufacturing Practice (GMP)
K4 the importance of wearing appropriate personal protection equipment (PPE) for scientific or technical activities
K5 the business objectives and the planning process for the formulation work you are to carry out
K6 the essential features of a work plan and how to create one
K7 how to write and use risk assessments to identify hazards associated with the work plan and what action to take
K8 why it is important to accurately follow a work plan and the consequences of not doing so
K9 the range of equipment used for the preparation of formulations
K10 how to choose the appropriate equipment for the scale, accuracy and precision required for the task
K11 how to calibrate the equipment to be used and conduct performance checks
K12 when to utilise an automated process
K13 the specifications of the raw materials and how to check them
K14 the range of methods used to prepare solid and liquid formulations
K15 the operating conditions that are necessary to prepare formulations, and how to maintain them
K16 the environmental conditions during preparation that may affect product performance
K17 the concepts of repeatability and reproducibility
K18 how to sample a prepared formulation for subsequent analysis
K19 the methods used for labelling samples in the workplace to include a traceable name, reference number, materials hazards and relevant dates
K20 the protocols for avoiding cross contamination across materials and equipment
K21 the methods that can be used for dealing with the handling, storage and disposal of materials
K22 the document control and reporting procedures that should be used

K23 why it is important to follow the correct data recording and reporting procedures
K24 the recording and reporting procedure in the event of deviations from work plan
K25 the types of investigation used to review the effectiveness or appropriateness of methods, action and results of the scientific or technical work
K26 the limits of your own authority and to whom you should report if you have problems that you cannot resolve
K27 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
K28 the reasons why effective communication is important, and the methods used for communicating effectively

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