



Australian Government

Department of Education, Employment and Workplace Relations

FDFPH2002A Operate a concentration process

Revision Number: 1

FDFPH2002A Operate a concentration process

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down processes used to concentrate liquid products.
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Application of the Unit

Application of the unit	This unit applies to production operators working in the pharmaceutical sector. This person would typically work within defined Good Manufacturing Practice (GMP) programs and procedures.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.
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Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.
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Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Prepare the concentration equipment and process for operation	1.1. Materials and services are confirmed to meet production requirements 1.2. Workplace documentation relevant to work area activities is identified and followed 1.3. The required facilities, storage, equipment and personnel are available 1.4. Line clearance procedures have been carried out 1.5. Procedures to eliminate or control the risk of cross-contamination are followed 1.6. The concentration process is set up and started up in accordance with workplace practices
2. Operate and monitor the concentration process	2.1. The concentration process is monitored to confirm that specifications are met 2.2. Out-of-specification product/process is identified, rectified and/or reported to maintain the process within specification 2.3. The work area is maintained according to housekeeping standards 2.4. Work is conducted according to environmental standards 2.5. Workplace documentation is maintained according to workplace reporting requirements
3. Shut down the concentration process	3.1. The process is shut down according to workplace procedures and practices 3.2. Maintenance requirements are identified and reported according to workplace reporting requirements

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Ability to:

- select, fit and use personal protective clothing and/or equipment
- conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, confirming that equipment is clean and correctly configured for processing requirements, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and turning on oil pumps to the evaporator, and pre-running equipment in line with operating temperature requirements where required
- start, operate, monitor and adjust process to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as:
 - product and machine temperature
 - vacuum
 - distillate colour
 - viscosity of concentrate
- take corrective action in response to out-of-specification results
- respond to and/or report equipment failure within level of responsibility
- demonstrate batch/product changeovers including line clearance procedures
- clean and sanitise equipment as required
- sort, collect, treat, recycle or dispose of waste
- complete workplace records as required
- maintain work area to meet housekeeping standards
- use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor
- work cooperatively within a culturally diverse workforce

Required knowledge

Knowledge of:

- purpose and principles of each stage of the concentration process, including the effect of heat and vacuum on distillate volume
- basic operating principles of the equipment, such as main equipment components and equipment operating capacities and applications
- services required and action to take if services are not available
- quality requirements of materials and the effect of variation on the concentration process

REQUIRED SKILLS AND KNOWLEDGE

- process specifications, procedures and operating parameters for different products/materials
- operating requirements and parameters and corrective action required where operation is outside specified operating parameters
- typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
- methods used to monitor the concentration process, such as inspecting, measuring and testing as required by the process, and the ability to calculate yields and determine the number of passes required to ensure concentration is within specification
- contamination/food safety risks associated with the concentration process
- common causes of variation and corrective action required
- occupational health and safety (OHS) hazards and controls, including the risks involved with the use of solvents such as ethanol, and the limitations of protective clothing and equipment used
- concentration process shut down procedures and responsibilities
- line clearance procedures, including procedures for cleaning feed lines
- environmental issues and controls relevant to the concentration process, including waste collection and handling procedures related to the process
- cleaning and sanitation procedures
- workplace documentation and authorisation procedures

Evidence Guide

EVIDENCE GUIDE

The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.

Overview of assessment

Assessment may occur in a real or simulated workplace. Where a simulated environment is used, it should provide access to workplace documentation, plus liquid extracts to be concentrated, concentration equipment and services.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

Evidence of ability to:

- prepare the concentration process for operation, including following line clearance procedures
- start up, operate and monitor equipment to produce concentrate within specifications
- maintain all necessary records.

Context of and specific resources for assessment

Assessment must occur in a real or simulated workplace where the assessee has access to:

- workplace documentation relating to concentration process and procedures.

Method of assessment

Assessors must be satisfied that the person can consistently perform the unit as a whole, including all elements, performance criteria, and required skills and knowledge. A holistic approach should be taken to the assessment.

Assessment of this unit would typically involve observation of the operator preparing, operating and shutting down the concentration process to meet production requirements. Observation should be sufficient to confirm consistent performance.

Guidance information for assessment

To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period of time in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

Range Statement

RANGE STATEMENT

The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.

Policies and procedures	Work activities are carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements and industrial awards and agreements
Workplace documentation	Workplace documentation relevant to work area activities include: • specifications • manufacturing formulae • processing instructions • batch production records • standard operating procedures (SOPs) • OHS information including material safety data sheets (MSDS)
Legislative requirements	Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • legislative and licensing requirements • Therapeutic Goods Act • weights and measures legislation • legislation relating to OHS, environmental management, equal opportunity and affirmative action, industrial awards and agreements
Materials	Materials include: • feed liquor/liquids products • ethanol • distillate • water
Equipment	Equipment may include: • centrifugal evaporator and collecting vessels (the evaporator may or may not be in line with

RANGE STATEMENT	
	heat exchanger) Service equipment also includes: • boilers and cooling towers
Cleaning and sanitation	Cleaning and sanitation procedures may include: • cleaning in place procedures for cleaning equipment, involving cleaning with remaining distillate, rinsing with water, caustic cleaning and rinsing with water till machine is neutralised

Unit Sector(s)

Unit sector	Pharmaceutical manufacturing
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Competency field

Competency field	
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Co-requisite units

Co-requisite units		