Australian Government

Department of Education, Employment and Workplace Relations

FDFPH2004A Operate a separation process using chromatography

Revision Number: 1

FDFPH2004A Operate a separation process using chromatography

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 a chromatography process where this process is used in production contexts.

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.

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		
	FDFOP2032A	Work in a clean room environment

Employability Skills Information

Employability skills	This unit contains employability skills.

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.

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Prepare the chromatography equipment for operation	1.1. Workplace documentation relevant to work area activities is identified and followed 1.2. Equipment is cleaned, assembled and adjusted to meet operational requirements 1.3. Equipment components and related instrumentation are set to meet production requirements 1.4. Column status is checked and ready for operation 1.5. Pre-start checks are carried out as required by work practices 1.6. Equipment status reports are completed as required by workplace system
2. Prepare the samples and load product	2.1. Pre-sampling tests are conducted according to test method to confirm column operation 2.2. Tests results are interpreted 2.3. Out-of-specification results are identified, investigated to identify cause and reported according to workplace procedures 2.4. Product is loaded into columns
3. Operate and monitor the column operation	3.1. The process is started and operated according to work practices 3.2. Equipment is monitored to confirm that process cycles occur in the correct sequence 3.3. Variation in equipment operation and process outcomes is identified and promptly reported according to workplace reporting procedures 3.4. Separation of solution meets specifications 3.5. Workplace documentation is maintained according to workplace reporting requirements 3.6. Work is conducted in accordance with workplace environmental guidelines
4. Shut down the column process	4.1. The process is shut down according to workplace procedures 4.2. 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, including gowning up, following required work area entry and exit procedures and moving around the work area to minimise risk of contamination
- prepare equipment for operation, such as inspecting equipment condition to identify any signs of wear, disinfecting and sterilising equipment and surfaces, assembling columns, confirming that connections and valves are correctly positioned, ensuring column lines have been purged and all safety guards are in place and operational, selecting instrumentation settings, cancelling isolation or lock outs as required, and conducting pre-start checks to check equipment readiness
- carry out sample testing to confirm integrity of columns (this is typically done by conducting a Height Equivalent to Theoretical Plate (HETP) test)
- demonstrate procedure for loading/packing product into columns
- start, operate, and monitor the process to achieve required outcomes, including monitoring:
  - chromatography cycles
  - correct collection of fractions as required
  - appropriate product segregation
  - pump operation
- take corrective action in response to out-of-specification results
- maintain security, integrity and traceability of samples, sub-samples and documentation
- respond to and/or report equipment failure within level of responsibility
- locate emergency stop functions on equipment
- follow isolation and lock out/tag out procedures as required to take process and related equipment off line in preparation for cleaning and/or maintenance within level of responsibility
- demonstrate product/process changeovers, including demonstrating column storage procedures
- follow end of batch procedures including line clearance and cleaning, yield calculation, materials reconciliation and product labelling
- 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

REQUIRED SKILLS AND KNOWLEDGE
• work cooperatively within a culturally diverse workforce
Required knowledge
Knowledge of: • purpose and principles of chromatography, including process, purpose and methods used for analysis and preparation • basic operating principles of chromatography equipment, such as main equipment components, consequences of incorrect equipment preparation (i.e. incorrectly positioned non-return valve, supply pump failure and air in the column) • quality characteristics and legal requirements to be achieved by the separation process • 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 • sample test methods and action required if results are out-of-specification (i.e. action required if the HETP fails) • procedures to collect fractions as appropriate to columns and process requirements • procedures to identify traces as required and corrective action where traces are not within specification • typical profile for a product cycle and the events to be monitored during the cycle • procedures used to ensure product segregation • analysis and interpretation of relevant test results and implications for action required • GMP/Good Laboratory Practice (GLP) requirements associated with chromatography process and related control measures • common causes of variation and corrective action required • occupational health and safety (OHS) hazards and controls, including the limitations of protective clothing and equipment used • procedures and requirements of different shutdowns, including an understanding of the requirements for column storage, emergency and routine shutdowns and procedures to follow in the event of power outage • line clearance, cleaning and sanitation procedures • isolation, lock out and tag out procedures and responsibilities • procedures and responsibilities for reporting production and performance information

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 must be carried out in a manner that recognises the cultural and literacy requirements of the assessee and is appropriate to the work performed. Competence in this unit must be achieved in accordance with food safety standards and regulations.
Critical aspects for assessment and evidence required to demonstrate competency in this unit	Evidence of ability to: • perform sample testing to confirm integrity of columns • start up, operate and monitor chromatography process to ensure separation of solutions to meet 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 separation process and procedures • chromatography equipment • typical range of samples to be tested • personal protective clothing and equipment • work procedures including advice on safe work practices, food safety, quality and environmental requirements.
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 separation 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

EVIDENCE GUIDE	
	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
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
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)
Equipment	Chromatography equipment includes: • columns • flow meters • UV meters • filters and air sensors Methods may include: • ion exchange • gel filtration

RANGE STATEMENT	
	• size exclusion filtration

Unit Sector(s)

Unit sector	Pharmaceutical manufacturing

Competency field

Competency field	

Co-requisite units

Co-requisite units		