



Australian Government

FBPPHM3010 Operate a compressing process

Release: 1

FBPPHM3010 Operate a compressing process

Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

Application

This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a tablet compressing process in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) and operating principles to the compressing process. Individuals work under broad direction and take responsibility for their own work.

No occupational licensing, legislative or certification requirements apply to this unit at the time of publication.

Pre-requisite Unit

Nil

Unit Sector

Pharmaceutical (PHM)

Elements and Performance Criteria

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
1. Prepare the compressing process for operation	1.1 Confirm materials and equipment are available and meet production requirements 1.2 Select and fit personal protective equipment and contamination prevention clothing according to workplace procedures 1.3 Fit and adjust machine components and attachments according to production requirements and equipment operation and maintenance manual

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	1.4 Enter processing and operating parameters according to safety and production requirements 1.5 Conduct pre-start checks according to workplace requirements
2. Operate and monitor the compressing process	2.1 Start up and monitor compressing process to confirm specifications are within required limits 2.2 Identify and report out of limit tablet products or processes according to workplace procedures 2.3 Maintain work area according to workplace cleaning standards 2.4 Conduct process according to safety and environmental requirements 2.5 Contain, remove and report spillages according to workplace procedures 2.6 Complete documentation according to workplace requirements
3. Shut down the compressing process	3.1 Confirm the workplace procedures for shutting down the process 3.2 Complete end-of-batch procedures according to batch instructions and workplace procedures 3.3 Safely shut down the process 3.4 Complete records according to workplace procedures

Foundation Skills

This section describes those language, literacy, numeracy and employment skills that are essential for performance in this unit of competency but are not explicit in the performance criteria.

Skill	Description
Reading	Identify relevant information from workplace documentation and interpret requirements for the compressing process
Writing	Complete workplace documentation using appropriate language and in required format

Skill	Description
Numeracy	Interpret production requirements for type and number of tablets to be compressed
Navigate the world of work	Identify workplace procedures relevant to own role
Interact with others	Report operational and safety information to relevant personnel using required communication method
Get the work done	- Plan, organise and implement tasks required to achieve production outcomes - Use problem-solving skills to analyse product and process faults and decide on appropriate action

Range of Conditions

This section specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included.

Pre-start must include:	- carrying out required area or line clearances - inspecting equipment condition to identify signs of wear - confirming all safety equipment is in place and operational - confirming that equipment is clean or sanitised - confirming that equipment is correctly configured for processing requirements.
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Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3010 Operate a compressing process	FDFPH2008A Operate a compressing process	Updated to meet Standards for Training Packages Changes to performance criteria for clarity Code changed to reflect AQF alignment	Equivalent unit

Links

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>

Assessment Requirements for FBPPHM3010 Operate a compressing process

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Performance Evidence

An individual demonstrating competency in this unit must satisfy all the elements and performance criteria of this unit.

There must be evidence that the individual has safely operated at least one tablet compressing process, including:

- selected, fitted and used personal protective equipment and contamination prevention clothing
- conducted pre-start checks required for the safe operation of the compressing process, including:
 - carrying out required area or line clearances
 - inspecting equipment condition to identify signs of wear
 - confirming all safety equipment is in place and operational
 - confirming that equipment is clean or sanitised
 - confirming that equipment is correctly configured for processing requirements
- started, operated, monitored and adjusted a tablet compressing process to achieve required outcomes
- conducted in-process control checks to confirm the process remains within limits
- sampled and inspected tablets for defects
- taken corrective action in response to a non-conformance
- followed end-of-batch procedures, including:
 - line clearance and cleaning
 - product labelling
- safely shut down the process according to workplace procedures
- cleaned and maintained work area to meet workplace cleaning standards and environmental requirements
- completed records according to workplace procedures.

Knowledge Evidence

An individual must be able to demonstrate the knowledge required to perform the tasks outlined in the elements and performance criteria of this unit. This includes knowledge of:

- stages of the tablet compressing process, including:
 - the purpose, methods and outcomes of each stage
 - stages and changes that occur during compression of tablets
 - the purpose and characteristics of ingredients and raw materials used in tablet production
 - types of raw materials used in the compressing process, and related handling and segregation requirements, including handling of hazardous goods
- basic operating principles, requirements and parameters of compressing equipment, including:
 - main equipment components, operating capacities and applications
 - typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
 - status and purpose of guards
 - the purpose and location of sensors and related feedback instrumentation
 - flow of the compressing process and the effect of outputs on downstream pharmaceutical processes
 - corrective actions required where operation is outside specified operating parameters
- operating principles of process control, including the relationship between control panels and systems and physical equipment
- functions and limitations of personal protective clothing and equipment, including:
 - protective gowns, scrubs, smocks, statcoats or disposable coveralls
 - surgical masks
 - surgical gloves
 - disposable overshoes
 - hair nets
- pre-start checks requirements, including:
 - carrying out required area or line clearances
 - inspecting equipment condition to identify signs of wear
 - confirming all safety equipment is in place and operational
 - confirming that equipment is clean or sanitised
 - confirming that equipment is correctly configured for processing requirements
- methods used to monitor compressing process, including inspecting measuring and testing
- product and process changeover procedures and responsibilities
- end-of-batch procedures, including:
 - calculating yield
 - materials reconciliation
- product labelling responsibilities and procedures
- requirements of different shutdowns, including:

- emergency and routine shutdowns
- procedures to follow in the event of a power outage
- line clearance procedures, including cleaning and sanitation procedures
- isolation, lock out and tag out procedures and responsibilities
- Good Manufacturing Practice (GMP) requirements associated with the compressing process and related control measures
- environmental issues and controls relevant to the compressing process, including waste collection and handling procedures
- requirements for completion of workplace documentation.

Assessment Conditions

Assessment of skills must take place under the following conditions:

- physical conditions:
 - a pharmaceutical manufacturing workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
 - personal protective equipment and contamination prevention clothing compressing process equipment
 - sampling and testing equipment
 - materials required for the compressing process
 - cleaning materials and equipment associated with compressing process
 - record keeping system
- specifications:
 - batch instructions including product specifications, control points and processing parameters
 - recording requirements and procedures
 - workplace documentation relating to a tablet compressing process and procedures that comply with GMP requirements
 - information on equipment capacity and operating parameters
 - sampling schedules and test procedures
 - cleaning procedures associated with compressing process.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.

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