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PHARMACEUTICAL MANUFACTURING TECHNICIAN



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COMPETENCY STANDARDS

National Vocational Certificate Level 1-4

Version 1 - November, 2019



Implemented by

giz Deutsche Gesellschaft
für Internationale
Zusammenarbeit (GIZ) GmbH

Published by

National Vocational and Technical Training Commission
Government of Pakistan

Headquarter

Plot 38, Kirthar Road, Sector H-9/4, Islamabad, Pakistan
www.navttc.org

Responsible

Director General Skills Standard and Curricula, National Vocational and Technical Training Commission
National Deputy Head, TVET Sector Support Programme, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Layout & design

SAP Communications

Photo Credits

TVET Sector Support Programme

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This document has been produced with the technical assistance of the TVET Sector Support Programme, which is funded by the European Union, the Federal Republic of Germany and the Royal Norwegian Embassy and has been commissioned by the German Federal Ministry for Economic Cooperation and Development (BMZ). The Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH in close collaboration with the National Vocational and Technical Training Commission (NAVTTTC) as well as provincial Technical Education and Vocational Training Authorities (TEVTAs), Punjab Vocational Training Council (PVTC), Qualification Awarding Bodies (QABs)s and private sector organizations.

Document Version

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Introduction

Pakistan has a vibrant and forward-looking Pharmaceutical Industry. It has the potential to provide job opportunities, grow exports and develop sustainable economic growth, provided with the correct and consistent policy directions by the regulators and government. About 90% of all medicines are locally manufactured and Manufacturers are responsible for ensuring that their products are manufactured to meet all the quality standards and in accordance with the Current Good Manufacturing Practice (CGMP) regulations. Pharmaceutical Sector is the largest employer of skilled and semi-skilled labor (male & female) alongside employment of university pass out pharmacy graduates. Technological changes in the industrial sector have greatly altered existing educational programs in technical and industrial vocational training with the provision of skilled workforce through the Competency Based Training & Assessment (CBT&A) Approach. Such programs provide abilities and interests among students and give assurance of trained workforce to industry.

Being cognizant of the importance of the Pharmaceutical Industry for the economy and the gap in skilled workforce, National Vocational & Technical Training Commission (NAVTTTC) developed National Competency Standards (NCSs) for Pharmaceutical Manufacturing Technician (PMT). These Competency Standards have been developed by the Qualifications Development Committee (QDC) established by the NAVTTTC that specify skills, knowledge and attitude in terms of benchmarks.

The National Competency Standards cover all the generic, functional and technical competencies expected from Pharmaceutical Manufacturing Technician (PMT). Apart from technical competencies required for manufacturing of tablets, capsules, liquid dosages and parenteral, these competency standards enable the technician to maintain work safety and develop good communication skills.

The NCSs for Pharmaceutical Manufacturing Technician (PMT) have been validated by the pharmaceutical industry and national vocational qualifications have been packaged from Level-1 to Level-4 according to the NVQF Manual-1 to ensure vertical and horizontal progression in this sector. The NAVTTTC's endorsed National Competency Standards (NSCs) for Pharmaceutical Manufacturing Technician will provide the basis for further development of curricula, assessment materials and instructional materials that will support implementation of competency-based training and assessment at institutional level.

Purpose of the qualification

In this training program trainees will learn and acquire specialized knowledge and practical skills required to function as a Pharmaceutical Manufacturing Technician in pharmaceutical industry. Technicians will be responsible to follow the process and procedures involved in the formulation of dosages forms of medicines such as tablets, capsules, parenterals, creams, ointments etc. Pharmaceutical Manufacturing Technicians are involved to maintain personal safety, maintenance of equipment and also ensure quality work. The specific objectives of this training course are as under:

- Improve the overall quality of training delivery and setting national benchmarks for training of pharmaceutical technicians in the country
- Provide flexible pathways and progressions to learners enabling them to receive
- relevant, up-to-date and recent skills
- Provide basis for competency-based assessment which is recognized and accepted by employers
- Establish a standardized and sustainable system of training for pharmaceutical technicians in the country

Date of validation

These national qualifications have been validated by the Qualifications Validation Committee (QVC) on 8-9 December, 2018 in Peshawar and 30th August, 2019 in Lahore which, will remain currency until August, 2022.

Date of review

These national qualifications may be reviewed in December, 2021.

Code of qualification

The International Standard Classification of Education (ISCED) is a framework for assembling, compiling, and analyzing cross-nationally comparable statistics on education and training, ISCED codes for these qualifications as assigned as follow:

Qualification Title	Code
National Vocational Certificate Level – 1 (Pharmaceutical Manufacturing Helper)	0916PHR02
National Vocational Certificate Level – 2 (Assistant Technician)	0916PHR03
National Vocational Certificate Level – 3 (Pharmaceutical Manufacturing Junior Technician)	0916PHR04
National Vocational Certificate Level - 4 (Pharmaceutical Manufacturing Technician)	0916PHR05

QUALIFICATIONS DEVELOPMENT COMMITTEE

The Qualifications Development Committee consisted of following members:

Sr. No	Name	Organization
1	Mr. Muhamad Ashfaq Paracha	Delta Pharma, Nowshera
2	Mr. Muhammad. Tahir Khan	Delta Pharma, Nowshera
3	Mr. Imran Khan	Stanley Pharma, Peshawar
4	Mr. Altaf Qadar	Stanley Pharma, Peshawar
5	Mr. Umar Farooq	Sarhad University, Peshawar
6	Mr. Fazle Amin	Sarhad University, Peshawar
7	Mr. Muhammad Nasir Khan	EX DD, SS&C NAVTTC, DACUM Facilitator
8	Mr. Shahid Anwar	Alen Pharma, Nowshera

QUALIFICATIONS VALIDATION COMMITTEE
--

The Qualifications Validation Committee consisted of following members:

Sr. No	Name	Organization
1	Mr. Muhammad Ashfaq Paracha	Vice President, KP Pharmaceutical Manufacturing Association / Delta Pharma, Pvt, Ltd, Nowshera
2	Mr. Muhammad Aslam Bangash	Dr. Raza Pharma, Pvt, Ltd, Peshawar
3	Mr. Imran Khan	Stanley Pharma, Pvt, Ltd, Peshawar
4	Mr. Altaf Qadir	Stanley Pharma, Pvt, Ltd, Peshawar
5	Mr. Umar Farooq	Sarhad University, Peshawar
6	Dr. Syed Muhammad Hassan Shah	Sarhad University, Peshawar
7	Mr. Shahid Anwar	Alen Pharma, Pvt, Ltd, Nowshera
8	Mr. Tahir Khan	Delta Pharma, Pvt, Ltd, Nowshera
9	Mr. Muhammad Arif	Astellas Pharma, Pvt, Ltd, Peshawar
10	Syed Roman Shah	Stanley, Pharma, Pvt, Ltd, Peshawar)
11	Mr. Nasir Khan	Paramedic Institute, Peshawar
12	Mr. Mazhar Taimur	CSH-North Pharma, Pvt, Ltd, Peshawar
13	Mr. Israr Ahmad	KP TEVTA, Peshawar
14	Mr. Muhammad Bias	KP TEVTA, Peshawar
15	Mr. Sajjad Ali Khan	Islamabad Institute of Paramedics, Peshawar
16	Mr. Muhammad Nasir Khan	EX- Deputy Director, SS&C NAVTTC (DACUM Facilitator)
17	Mr. Tariq Nazir	Managing Director. Sambro Pharmaceuticals, Lahore

Entry Level

The entry requirement in Level - 1 NVQ is Matric Science or equivalent to Matric, preferably F.Sc.

Regulations for the qualification and schedule of units

Not Applicable.

Categorization and Levelling of the Competency Standards

Code	Name of Duty or (Module)	Level	Credit	Category
102200843	Comply with Work Health and Safety Policies	1	03	Generic
041700838	Obey the Workplace Policies and Procedures	1	02	Generic
001100850	Follow Basic Communication Skills (General)	1	05	Generic
061100855	Operate Computer Functions(General)	1	05	Generic
091600735	Adopt Basic Good Manufacturing Practices for Pharmaceutical Production	1	05	Technicaql
102200844	Comply Personal Health and Safety Guidelines	2	03	Generic
041700839	Communicate the Workplace Policy and Procedure	2	02	Generic
001100851	Perform Basic Communication (Specific)	2	03	Generic
061100856	Perform Basic Computer Application (Specific)	2	04	Generic
091600602	Prepare work environment according to manufacturing order	2	04	Technical
091600603	Receive product raw materials according to manufacturing order	2	05	Technical
091600604	Adjust machine as per product manufacturing order	2	08	Technical
102200846	Apply Work Health and Safety Practices (WHS)	3	02	Generic

041700840	Identify and Implement Workplace Policy and Procedures	3	01	Generic
001100852	Communicate at Workplace	3	01	Generic
061100858	Perform Computer Application Skills	3	01	Generic
041300867	Manage Personal Finances	3	01	Generic
091600606	Manufacture tablets	3	31	Technical
091600607	Manufacture capsules and dry suspensions	3	10	Technical
091600608	Manufacture liquid dosages	3	15	Technical
091600609	Perform packaging as per manufacturing order	3	07	Technical
102200848	Contribute to Work Related Health and Safety (WHS) Initiatives	4	03	Generic
041700841	Analyze Workplace Policy and Procedures	4	03	Generic
001100853	Perform Advanced Communication	4	03	Generic
061100858	Develop Advance Computer Application Skills	4	04	Generic
041300869	Manage Human Resource Services	4	02	Generic
041300860	Develop Entrepreneurial Skills	4	03	Generic
091600611	Manufacture Parenterals	4	40	Technical
091600612	Ensure quality products	4	04	Functional
091600613	Complete Production Documentation	4	04	Functional

Packaging of Qualifications

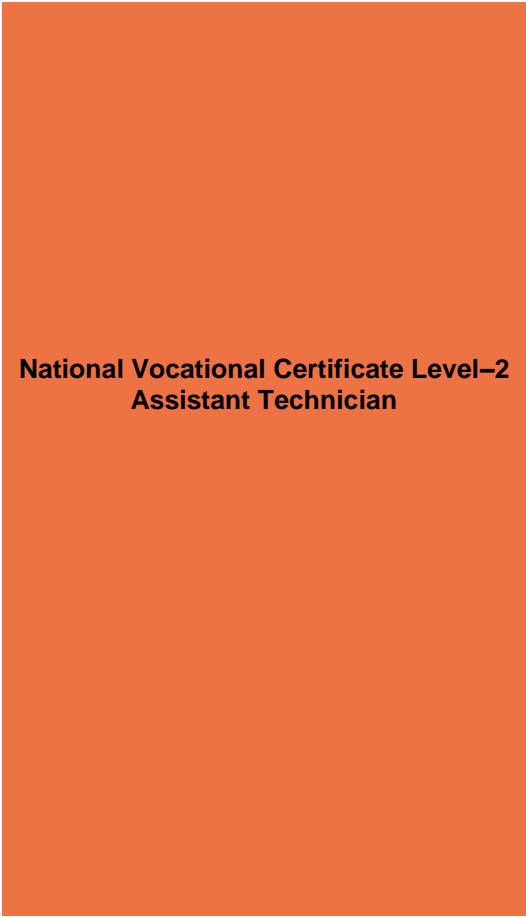
The National Vocational Qualifications have been packaged as detailed below:

National Vocational Certificate Level-4 Pharmaceutical Manufacturing Technician	091600613	Complete Production Documentation
	091600612	Ensure quality products
	091600611	Manufacture Parenterals
	041300860	Develop Entrepreneurial Skills
	041300869	Manage Human Resource Services
	061100858	Develop Advance Computer Application Skills
	001100853	Perform Advanced Communication
	041700841	Analyze Workplace Policy and Procedures
	102200848	Contribute to Work Related Health and Safety (WHS) Initiatives
	National Vocational Certificate Level-3 Pharmaceutical Manufacturing Junior Technician	091600609
091600608		Manufacture liquid dosages
091600607		Manufacture capsules and dry suspensions
091600606		Manufacture tablets
041300867		Manage Personal Finances
061100858		Perform Computer Application Skills



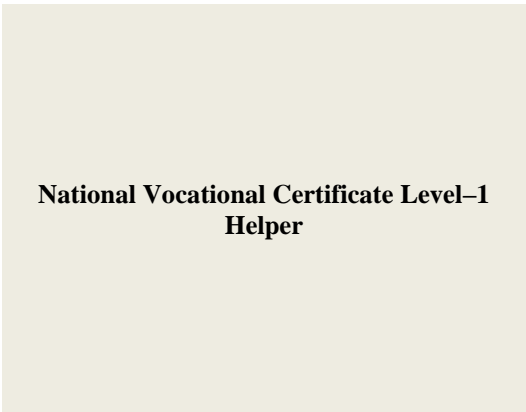


- 001100852 Communicate at Workplace
- 041700840 Identify and Implement Workplace policy and Procedures
- 102200846 Apply Work Health and Safety Practices (WHS)



**National Vocational Certificate Level-2
Assistant Technician**

- 091600604 Adjust machine as per product manufacturing order
- 091600603 Receive product raw materials according to manufacturing order
- 091600602 Prepare work environment according to manufacturing order
- 061100856 Perform Basic Computer Application (Specific)
- 001100851 Perform Basic Communication (Specific)
- 041700839 Communicate the Workplace Policy and Procedure
- 102200844 Comply Personal Health and Safety Guidelines



**National Vocational Certificate Level-1
Helper**

- 091600735 Adopt Basic Good Manufacturing Practices for Pharmaceutical Production
- 061100855 Operate Computer Functions(General)
- 001100850 Follow Basic Communication Skills (General)
- 041700838 Obey the Workplace Policies and Procedures

102200843 Comply with Work Health and Safety Policies

102200843 Comply with Work Health and Safety Policies

Overview: This unit describes the performance outcomes, skills and knowledge required to apply general work health and safety requirements in the workplace. Communicate work and health safety assess at work place. It describes generic work health and safety responsibilities applicable to employees without managerial or supervisory responsibilities.

Competency Units	Performance Criteria
CU1. Work safely at work place	<p>P1. Identify relevant organizational safety policies and procedures</p> <p>P2. Categorize tools and equipment as per requirements</p> <p>P3. Maintain tools and equipment</p> <p>P4. Follow established safety procedures during work activities</p> <p>P5. Identify existing or potential safety issues to designated persons</p> <p>P6. Report work-related incidents and accidents to supervisor</p> <p>P7. Take necessary measures to minimizing risks</p>
CU2. Communicate work health and safety (WHS) assess at work place	<p>P1. Raise work health and safety issues with supervisor.</p> <p>P2. Contribute to workplace meetings and other consultative processes for work health and safety management at the workplace</p> <p>P3. Make suggestions for improving work health and safety practices</p>
CU3. Minimize risks to personal safety at work place	<p>P1. Identify situations that may endanger the personal safety</p> <p>P2. Document the incident regarding personal safety at work place</p> <p>P3. Eliminate workplace hazards regarding personal safety</p> <p>P4. Identify damaged items and equipment for personal safety</p> <p>P5. Notify supervisor regarding damaged items and equipment for personal safety</p>
CU4. Minimize risks to public safety	<p>P1. Identify situations that may endanger the public safety</p> <p>P2. Document the incident at work sites</p> <p>P3. Eliminate workplace hazards at work sites</p> <p>P4. Identify damaged items and equipment related to public safety</p> <p>P5. Notify Situation that may endanger situation for safety measures.</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Identify the commonly used tools and equipment used at workplace.
- K2:** Rights and responsibilities of employers and employees
- K3:** Consultative processes to manage and monitor health and safety issues to enable active participation in maintaining a safe workplace
- K4:** State potential hazards in the workplace
- K5:** State commonly used hazard signs and safety symbols

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

Identify health and safety policies to maintain and avoid any unwanted incident.

041700838 Obey the Workplace Policies and Procedures

Overview: This unit describes the skills and knowledge required to develop and implement a workplace policy & procedures and to modify the policy to suit changed circumstances. It applies to individuals with managerial responsibilities who undertake work developing approaches to create, monitor and improve strategies and policies within workplaces and engage with a range of relevant stakeholders and specialists.

Competency Units	Performance Criteria
CU1. Obey the workplace personal appearance and hygiene	<p>P1. Wear suitable clothes for the workplace and respect local and cultural contexts</p> <p>P2. Meet specific company dress code requirements</p>
CU2. Follow work ethics	<p>P1. Follow company value/ ethics code/ conduct policies and guidelines</p> <p>P2. Use company resources in accordance with company ethical standards</p> <p>P3. Conduct personal behavior and relationships in accord with company policy & procedures</p> <p>P4. Demonstrate ethical behavior with co-workers</p> <p>P5. Report work incident situations or resolve accordingly</p>
CU3. Demonstrate the Work place behaviors	<p>P1. Practice the positive behavior</p> <p>P2. Avoid arguing</p> <p>P3. Adopt flexibility in behavior to accept the resistance</p>
CU4. Communicate workplace policy & procedures	<p>P1. Listen directions carefully</p> <p>P2. Ask relevant questions politely</p> <p>P3. Avoid to use abusive language/ expression</p> <p>P4. Respect co-workers and others</p>
CU5. Review the implementation of workplace policy & procedures	<p>P1. Ensure proper implementation of policies</p> <p>P2. Enlist the gaps for improvement</p> <p>P3. Follow the feedback, if any</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

K1: Rules, regulations and SOPs applicable to the organization

K2: Turnaround time to achieve target/goal.

K3: Operational hierarchal levels in an organization.

K4:

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

Follow work place policy personal appearances adopting company values/ ethics/ codes and broacher policies for ensuring work place SOP's

001100850 Follow Basic Communication Skills (General)

Overview: After successful completion of this module you will be able to listen attentively, develop non-verbal communication, and identify communication barriers, interview preparation for job and different communication platforms in the workplace and throughout your career.

This unit of competency is designed to manage the workers and other personnel that can help in improving work quality and quantity through basic communication skills

Competency Units	Performance Criteria
CU1. Adopt Effective listening to Skills	<p>P1. Listen attentively to others to improve communication skills</p> <p>P2. Avoid interrupting while listening others</p> <p>P3. Ask questions to ensure understanding</p> <p>P4. Receive and follow instructions as given by supervisor</p> <p>P5. Give the speaker regular feedback to communicate appropriately</p>
CU2. Develop Nonverbal communication with peers	<p>P1. Maintain eye contact to improve communication</p> <p>P2. Use facial expressions and gestures</p> <p>P3. Use Body language to communicate appropriately</p> <p>P4. Participate within Peers</p>
CU3. Prepare for Interview to get a job	<p>P1. Prepare yourself for interview to employer</p> <p>P2. Follow schedule according to the sequence of interview</p> <p>P3. Use communication techniques used while appearing in interview</p> <p>P4. Provide basic evidence of related skill</p> <p>P5. Respond appropriately to strong client emotional reactions</p>
CU4. Use communication platform at workplace	<p>P1. Convey message using different communication plate forms</p> <ul style="list-style-type: none"> • Face to face • Video chat • Phone calls/messages • Social Media
CU5. Identify communication barriers to improve interpersonal skills	<p>P1. Identify communication barriers to improve communication skills with each other i.e.</p> <ul style="list-style-type: none"> • Attitudinal barrier • Physical Barrier

	<ul style="list-style-type: none"> • Long differences • Conflicting information • Differing status, position /self-expression <p>P2. Use strategies to overcome these barriers in the client-counsellor relationship</p>
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Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out the tasks covered in this competency standard. This includes the knowledge of:

- K1:** Minimizing communication barriers
- K2:** Listening, and responding with an open mind in a more effective way.
- K3:** appropriate communication methods.
- K4:** verbal and non-verbal messages appropriately.
- K5:** Confidence building
- K6:** Body language
- K7:** Appropriate Voice tone
- K8:** Interpersonal skills
- K9:** listening Skills

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Find a job through social media resources
 1. Prepare yourself to appear in interview by following points:
 - Effective listening skills
 - Body language
- Work in groups of 3-5 members.
 1. Think of a situation when you tried to communicate with another person. Or when somebody tried to communicate with you, and it failed.
 2. Think about the problems or barriers that interfered with the communication.
 - List the reasons for failure identified by your group.
- Non-verbal communication
Have activity cards:

- Worried
- Happy
- Disappointed
- Laughing
- Annoying

Participants to draw one of the activity cards. Without speaking, communicate the feeling or emotion on the card to the rest of the group. Have one participant at time get up in front of the group.

061100855 Operate Computer Functions (General)

Overview: The competency Standard describe skills and knowledge required to setup a computer system, organize files in folders, and shutdown a computer system.

Competency Units	Performance Criteria
CU1. Set up the computer for use	<p>P1. Identify physical components of computer</p> <p>P2. Identify peripheral devices of the computer</p> <p>P3. Connect all components of computer</p> <p>P4. Follow procedures to turn on the computer system</p>
CU2. Organize files in folder	<p>P1. Create folders/subfolders with suitable names</p> <p>P2. Save files in relevant folders.</p> <p>P3. Rename and move folders in different drives.</p> <p>P4. Move folders and files using drag and drop techniques</p> <p>P5. Save folders and files on different media</p> <p>P6. Search for folders/subfolders and files using appropriate tool bars</p> <p>P7. Delete Folder files</p> <p>P8. Restore deleted folder files</p>
CU3. Shut down computer system	<p>P1. Save any work to be retained</p> <p>P2. Close open application programs correctly</p> <p>P3. Shut down computer</p> <p>P4. Switch off any unused peripheral devices</p> <p>P5. Ensure computer safety</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out the tasks covered in this competency standard. This includes the knowledge of:

- K1:** Basic parts of a computer
- K2:** Definition of computer
- K3:** Definition of Drives
- K4:** enlist computer component

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Switch on the computer
- Attach Computer component
- Switch on Peripheral devices
- Make a folder in any partition(drive) in hard disk
- Give name to the folder
- Save file in the folder
- delete the folder/File
- Shut down computer

The evidence should integrate employability skills with workplace tasks and job roles and verify competency is able to be transferred to other circumstances and environments

091600735 Adopt Basic Good Manufacturing Practices for Pharmaceutical Production

Overview: This Competency Standard identifies the competencies required to know and work under principles related to Current Good Manufacturing Practices (cGMP) at the workplace according to the industry's approved guidelines, procedures and interpret rules/regulations. The trainee understands and applies the basic requirements of GMP at workplace regarding Pharmaceutical quality system, Personnel, Premises and equipment, cGMP documentation and records, cGMP production and in-process controls, Quality control, Storage and distribution.

Trainee will be expected to perform these requirements under routine production and apply all necessary measures to comply with these. The underpinning knowledge regarding basic GMP will be sufficient to provide the basis for the job at workplace.

Competency Units	Performance Criteria
CU1. Apply basic cGMP requirements in regard to pharmaceutical quality system	<p>P1. Follow requirements of quality system within the production</p> <p>P2. Report to in-charge about any deviation if occur, for prompt measures</p>
CU2. Apply basic cGMP requirements in regard to personal hygiene measures	<p>P1. Perform proper hand washing and disinfection procedures before entering production</p> <p>P2. Report to supervisor in the case of illness</p> <p>P3. Remove personal articles (jewelry, watch, cell phone, etc.) before entering work area</p> <p>P4. Wear Personal Protective Equipment (PPE) as per SOPs regarding hygienic measures</p> <p>P5. Receive visitor following the visitors' policy</p>
CU3. Apply basic cGMP requirements in regard to premises and equipment	<p>P1. Follow procedures for flow of personnel, material flow and product flow</p> <p>P2. Fill out specifications, records, batch production records for production under supervision</p>

CU4. Apply basic cGMP requirements in regard to documentation and records	P1. Interpret laboratory control records P2. Follow master production instructions P3. Locate documents of external origin, if needed P4. Safeguard documents and records appropriately
CU5. Apply basic cGMP requirements in regard to production, quality control and in-process controls	P1. Follow master production instructions P2. Perform basic in-process control measurements (e.g. pH, weighing) under supervision P3. Perform basic quality control measure under supervision
CU6. Apply basic cGMP requirements in regard to storage and distribution	P1. Store materials and end product appropriately P2. Use appropriate packaging materials for end product

Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Explain safety rules and regulations for the pharmaceutical industry
- K2:** Know about responsibilities within the quality management system (e.g. production, quality assurance, quality control)
- K3:** Explain critical deviations during production
- K4:** Understand system of internal audit and responsibilities for self-inspection
- K5:** Understand concept of corrective action within the quality system
- K6:** Understand concept of continual improvement
- K7:** Know about hygienic measures (cGMP) for pharmaceutical production
- K8:** Explain work place specific guidelines for uniform
- K9:** Know about cross-contamination in regard to personal hygiene
- K10:** Explain the use of medical certificates
- K11:** Know about visitors' policy
- K12:** Understand clean room concept for pharmaceutical production
- K13:** Understand system of flow of materials, personnel and product
- K14:** Understand plant lay-out concepts for pharmaceutical production (e.g. straight-flow)

- K15:** Know about proper design and construction of process equipment
- K16:** Explain different types of contact surface for pharmaceutical production
- K17:** Know about equipment calibration and equipment adjustment
- K18:** Explain control of documents procedure
- K19:** Explain control of records procedure
- K20:** Explain distribution procedures
- K21:** Know about documents of external origin, SOPs, records, specification, master production instructions, batch production and control records, laboratory control records
- K22:** Know about documentation of completion
- K23:** Know about common process deviations
- K24:** Explain critical steps in production
- K25:** Explain in-process sampling and controls
- K26:** Know about contamination controls
- K27:** Know about packaging materials
- K28:** Explain warehouse procedures
- K29:** Explain distribution procedures

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

- Measure temperature and humidity of workplace/area
- Adjust lights in workplace/area
- Define Swab Test
- Describe standard specifications about the safety of workplace
- Knowledge about basic cGMP requirements for pharmaceutical production for
 - Pharmaceutical quality system
 - Personal hygiene
 - Premises and equipment
 - Documentation and records
 - Production, quality control and in-process controls
 - Storage and distribution

Tools and Equipment Required

The tools and equipment required for this competency standard are given below:

- Protective clothing
- In-process control measuring devices (e.g. pH-meter, scales)

102200844 Comply with Personal Health and Safety Guidelines

Overview: This Competency Standard identifies the competencies required to protect/apply occupational Safety, health and Environment at workplace according to the industry's approved guidelines, procedures and interpret environmental rules/regulations. Trainee will be expected to identify and use Personal Protective Equipment (PPE) according to the work place requirements. The underpinning knowledge regarding Observe Occupational Safety and Health (OSH) will be sufficient to provide the basis for the job at workplace.

Competency Units	Performance Criteria
CU1. Identify Personal Hazards at Workplace	P1: Identify risk to personal health P2: Identify hygiene and safety at work place P3: Identify processes P4: Identify tools, equipment and consumable materials that have the potential to cause harm P5: Report, identified risk to Health, hygiene and safety to concerned
CU2. Apply Personal Protective Safety Equipment (PPE) and Equipment	P1: List the Personal Protective equipment P2: Select personal protective equipment in terms of type and quantity according to work orders. P3: Wear personal protective equipment according to job requirements. P4: Clean personal protective equipment P5: Stored Personal Protective equipment in proper place after use.
CU3. Comply with Occupational Safety and Health (OSH)	P1: Maintain cleanliness and hygiene as per organizational policy P2: Comply with Health, hygiene and safety precautions before starting work P3: Comply with organizational Health, hygiene and safety guidelines during work P4: Deal with resolvable problems according to prescribed procedures P5: Report un resolvable problems to concerned P6: Place the tools equipment etc. at their prescribed place after completion of work

<p>CU4. Dispose of hazardous Waste/materials from the designated area.</p>	<p>P1: Identify hazardous waste materials which needs to be disposed off</p> <p>P2: Segregate hazardous or non-hazardous waste carefully from the designated area as per approved procedure</p> <p>P3: Use proper disposal hazardous containers for dispose-off hazardous waste as per procedure</p> <p>P4: Take necessary precautions like putting masks and gloves while disposing hazardous waste/ materials as per standard operating procedure</p>
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Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Explain safety rules and regulations of organization
- K2:** List Personal protection and safety Equipment
- K3:** Describe meaning of Safety signs and symbols
- K4:** Demonstrate understanding of safety related Standard Operating Procedure/guidelines
- K5:** Describe waste disposal SOPs
- K6:** Explain best practices relating to clean and safe work environment

Critical Evidence(s) Required

The candidate needs to produce following critical evidence (s) to be competent in this competency standard:

A person who demonstrates competency in this unit must be able to provide evidence of maintaining personal health and hygiene practices. The evidence should integrate employability skills with workplace tasks and job roles and verify competency is able to be transferred to other circumstances and environments.

041700839 Communicate the Workplace Policy and Procedure

Overview: This unit describes the performance outcomes, skills and knowledge required to develop communication skills in the workplace. It covers gathering, conveying and receiving information, along with completing assigned written information under direct supervision.

Competency Units	Performance Criteria
CU1. Identify workplace communication procedures	<p>P1. Identify organizational communication requirements and workplace procedures with assistance from relevant authority</p> <p>P2. Identify appropriate lines of communication with supervisors and colleagues.</p> <p>P3. Seek advice on the communication method/equipment most appropriate for the task</p>
CU2. Communicate at workplace	<p>P1. Use effective questioning, and active listening and speaking skills to gather and convey information</p> <p>P2. Use appropriate non-verbal behavior at all times</p> <p>P3. Encourage, acknowledge and act upon constructive feedback</p>
CU3. Draft Written Information	<p>P1. Identify and comply with required range of written materials in accordance with organizational policy and procedures</p> <p>P2. Draft and present assigned written information for approval, ensuring it is written clearly, concisely and within designated timeframes.</p> <p>P3. Ensure written information meets required standards of style, format and detail.</p> <p>P4. Seek assistance and/or feedback to aid communication skills development</p>
CU4. Review Documents	<p>P1. Check draft for suitability of tone for audience, purpose, format and communication style</p> <p>P2. Check draft for readability, grammar, spelling, sentence and paragraph construction and correct any inaccuracies or gaps in content.</p> <p>P3. Check draft for sequencing and structure</p> <p>P4. Check draft to ensure it meets organizational requirements</p> <p>P5. Ensure draft is proofread, where appropriate, by supervisor or colleague</p>

Knowledge and Understanding

- K1:** Key provisions of relevant regulations that may affect aspects of business operations, such as privacy laws
- K2:** Organizational policies, plans and procedures.
- K3:** Barriers to communication
- K4:** Communication model
- K5:** Verbal and written communication techniques

Critical Evidence(s) Required

A person who demonstrates competency in this unit must be able to provide evidence of the ability to develop communication skills in the workplace. It covers gathering, conveying and receiving information, along with completing assigned written information under direct supervision. The evidence should integrate employability skills with workplace tasks and job roles and verify competency is able to be transferred to other circumstances and environments.

001100851 Perform Basic Communications (Specific)

Overview: This unit describes the skills and knowledge required to assist in the development of communication competence by providing information regarding different forms of communication and their appropriate use.

By the end of this program, learners will be able, to communicate more effectively and efficiently by: working in a team, follow supervisor's instructions and develop generic communication work skills at workplace

Competency Units	Performance Criteria
CU1. Communicate in a team to achieve intended outcomes	<p>P1. Treat team members with respect</p> <p>P2. Maintain positive relationships to achieve common organizational goals</p> <p>P3. Get work related information from team</p> <p>P4. Identify interrelated work activities to avoid confusion</p> <p>P5. Adopt communication skills, which are designed in a team.</p> <p>P6. Identify problems in communication with a team</p> <p>P7. Resolve Communication barrier through discussion and mutual agreement</p>
CU2. Follow Supervisor's instructions as per organizational SOPs	<p>P1. Receive the instructions from Supervisor</p> <p>P2. Carry out the instructions of the supervisor</p> <p>P3. Report to the supervisor as per organizational SOPs</p>
CU3. Develop Generic communication skills at workplace	<p>P1. Develop basic reading skills</p> <p>P2. Develop Basic writing Skills</p> <p>P3. Develop basic listening skills</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out the tasks covered in this competency standard. This includes the knowledge of:

- K1:** Basic Learn and understand Types of communication
- K2:** Basic Reading Skills
- K3:** Basic Writing skills
- K4:** Basic Verbal communication skills
- K5:** Basic Problem solving skills

K6: Basic Self-Management Skills

K7: Basic Technology Skills

K8: Basic Interview Skills

K9: Basic Workplace dress code

K10: Basic The role of team members and functionality of the teams

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Make a list of appropriate communication skills with colleagues and supervisors

061100856 Perform Basic Computer Application (Specific)

Overview: This unit describes the skills and knowledge required to use spreadsheet to prepare a page of document, develops familiarity with Word, Excel, Access, PowerPoint, email, and computer graphics basics.

It applies to individuals who perform a range of routine tasks in the workplace using a fundamental knowledge of spreadsheets, Microsoft office and computer graphics in under direct supervision or with limited responsibility.

Competency Units	Performance Criteria
CU1. Create Word Documents	<p>P1. Open word processing application</p> <p>P2. Create a word document</p> <p>P3. Customize page layout with relevant name setting</p> <p>P4. Set up page in a word document</p> <p>P5. Edit word document as required</p> <p>P6. Use simple formatting tools when creating the document</p> <p>P7. Save word document to directory</p> <p>P8. Insert table in a word document</p> <p>P9. Insert appropriate images into document as necessary</p> <p>P10. Insert header/footer in a word document</p> <p>P11. Insert section break in a word document</p> <p>P12. Set style in word document</p> <p>P13. Select basic Print settings</p> <p>P14. Print the document</p>
CU2. Use internet for Browsing	<p>P1. Use search engines to open website</p> <p>P2. Search data on different topics</p> <p>P3. Refine search to increase relevance of information or content</p> <p>P4. Navigate a website to access the information or content required</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out the tasks covered in this competency standard. This includes the knowledge of:

- K1:** Describing formatting styles and their effect on formatting, readability and appearance of documents
- K2:** Outline purpose, use and function of word-processing software.
- K3:** Editing in MS Word
- K4:** Formatting in MS word
- K5:** Use of different search engines
- K6:** Use of different web pages

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Identify the components of computer
- Follow organizational ergonomic work health and safety (WHS) requirements and practices
- Create, open and retrieve documents using customized basic settings
- Format documents by creating tables and adding text, objects and images
- Save and prints documents.
- Download data through web browser

019600602 Prepare Work Environment According to Manufacturing Order

Overview: This Competency Standard identifies the competencies for conducting and maintain physical work environment that is without risks to technician's health and safety in pharmaceutical manufacturing process. The physical work environment such as, cleaning and sanitation of process equipment, workplace lighting, ventilation, environmental monitoring, such as proper temperature conditions, humidity, air control within the production areas are ensured for quality products

Competency Units	Performance Criteria
CU1. Maintain temperature and humidity	<p>P1. Inspect work place regularly as per area/product specific requirements</p> <p>P2. Note current temperature and humidity of workplace as required for manufacturing order</p> <p>P3. Maintain workplace temperature and humidity as per manufacturing order</p> <p>P4. Record temperature and humidity as per manufacturing order</p> <p>P5. Report to in-charge about any deviation if occur, for prompt measures</p> <p>P6. Perform measurements using manometer, dehumidifier</p>
CU2. Ensure air pressure of specific area/work place	<p>P1. Note and maintain air pressure of workplace as required for manufacturing order</p> <p>P2. Record air pressure as per manufacturing order</p> <p>P3. Report to in-charge about any deviation if occur, for prompt measures</p> <p>P4. Perform measurements using hygrometer, thermometer</p>
CU3. Conduct and verify cleaning and sanitation procedures	<p>P1. Clean workplace, tools/equipment from dust before swab test</p> <p>P2. Disinfect manufacturing area, tools/equipment's before swab test as per standard specifications</p> <p>P3. Report to in-charge about any deviation</p>

<p>CU4. Adjust light as per specifications in workplace area</p>	<p>P1. Identify high-bay and low-bay lights and colors as per manufacturing of sensitive medicine products or task specific lights in workplace</p> <p>P2. Adjust dust and water resistance lights as required for specific manufacturing tasks</p>
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Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Define hygrometer, thermometer as equipment
- K2:** Explain heating, ventilation, air pressure at workplace
- K3:** Define dehumidifier
- K4:** Describe Monometer
- K5:** Explain air pressure variations
- K6:** Know about standard air pressures
- K7:** Explain cleaning procedure
- K8:** Explain swab test to kill microorganisms
- K9:** Know the role of detergents & disinfectant in workplace
- K10:** Define sensitive products and their specifications
- K11:** Explain different types of lights color and specifications
- K12:** Explain industry Standard Operating Procedures (SOPs) related to environmental monitoring
- K13:** Explain heating, ventilation, air pressure at workplace
- K14:** Explain industry Standard Operating Procedures (SOPs) related to cleaning and sanitation procedures
- K15:** Explain industry Standard Operating Procedures (SOPs) related to cleaning and sanitation procedures
- K16:** Explain industry Standard Operating Procedures (SOPs) related to cleaning and sanitation procedures
- K17:** Explain industry Standard Operating Procedures (SOPs) related to cleaning and sanitation procedures
- K18:** Explain mechanism of Swab tests
- K19:** Know how to read MSDS (Material Safety Data Sheet) of detergents and Disinfectants

K20: Explain industry Standard Operating Procedures (SOPs) related to maintenance of buildings and facilities

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

- Measure temperature and humidity of workplace/area
- Adjust lights in workplace/area
- Define Swab Test
- Describe standard specifications about the safety of workplace

Tools and Equipment required

The tools and equipment required for this competency standard are given below:

- Heating ventilation and Air Conditioning (HVAC)
- Dehumidifier
- Sanitizer
- Manometer
- Maintenance of building and facilities manuals/ SOPs
- Cleaning and sanitation manual/SOPs
- Environmental monitoring manual/ SOP
- SWAB- Test

091600603 Receive Product Raw Materials according to Manufacturing Order (GMP: Materials Management)

Overview: This Competency Standard identifies the competencies required to apply skills and knowledge to perform manufacturing functions by a Pharmaceutical Technician in accordance with the industry's approved guidelines and procedures in regard to materials management as part of the good manufacturing practices for pharmaceutical production. Trainee will be expected to perform general controls, sampling and testing of incoming production materials, to identify labeled raw materials, weight, shifting, and arrange raw materials to perform mixing raw materials as per procedure. Furthermore, adequate storage of raw materials is part of this Competency Standard.

Competency Units	Performance Criteria
CU1. Receive of raw materials & storage	<p>P1. Perform sensory (visual) evaluation of raw materials (including packaging materials)</p> <p>P2. Cross check quality control approved report</p> <p>P3. Store raw materials in a manner to prevent degradation, contamination and cross-contamination</p>
CU2. Identify materials according to labels	<p>P1. Identify raw materials as per manufacturing order</p> <p>P2. Cross check the labels of raw materials as per specifications against each manufacturing order</p> <p>P3. Check the signature of appropriate authority on labeled raw materials as per manufacturing order</p> <p>P4. Report to in-charge about any deviation</p>
CU3. Check weight of raw materials	<p>P1. Confirm calibration status of weighing balance</p> <p>P2. Cross check the gross weight of individual labeled raw materials as per manufacturing order</p>
CU4. Shift materials to concerned section	<p>P1. Put the batch materials one by one in dispensing trolley as per manufacturing order for shifting to workplace area</p> <p>P2. Transfer dispensed materials trolley to the manufacturing area as per procedure</p> <p>P3. Check the temperature and humidity of material placement area as per procedure</p> <p>P4. Park trolley safely and lock it at appropriate place as per instructions</p>

<p>CU5. Arrange Raw Materials for Mixing</p>	<p>P1. Check the batch material trolley prior to dispatch to mixing area as per procedure</p> <p>P2. Transfer dispensed materials trolley to the production area as per instructions</p> <p>P3. Check the batch materials and arrange it according to mixing order as per set procedure</p> <p>P4. Retain the wet mixing materials in workplace area and take remaining materials to quarantine area as per procedure</p>
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Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Explain the identification of raw materials used in pharmaceutical industry
- K2:** Describe manufacturing order
- K3:** Describe different types (specifications) of raw materials
- K4:** Define calibration
- K5:** Describe the importance of calibration
- K6:** Explain calibration (internal/external)
- K7:** Define batch manufacturing order
- K8:** Explain safe shifting and mixing of material
- K9:** Describe different methods of arranging batch materials as per job order
- K10:** Define mixing procedure
- K11:** Explain wet mixing materials and how to quarantine it
- K12:** Explain industry Standard Operating Procedures (SOPs) related to materials management
- K13:** Know about relevant sampling and testing of incoming production materials according to industry best practices
- K14:** Know about storage conditions depending on the nature of the raw materials received
- K15:** Explain industry Standard Operating Procedures (SOPs) related to materials mixing

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

- The Raw materials identification
- Count ingredients of raw materials of tablets/capsule
- Define calibration
- Types of calibrations
- Identification and verification of raw materials
- Explain mixing procedure
- Random sampling and testing of active pharmaceutical ingredients
- Consistency in production and quality

Tools and Equipment required

The tools and equipment required for this competency standard are given below:

- Weighing balance
- Shifting Trolley

091600604 Adjust Machine as per Product Manufacturing Order

Overview: This Competency Standard identifies the competencies required to apply skills and knowledge to perform manufacturing functions in accordance with the industry's approved guidelines and procedures. Trainee will be expected to identify pharmaceutical machinery and perform machines adjustment for quality product as well as general housekeeping and maintenance of equipment.

Competency Units	Performance Criteria
CU1. Check Electrical and Mechanical parameters of Machine for Proper Functionality	<p>P1. Check machine electric input and output as per instructions given in machine manual</p> <p>P2. Check machine mechanically fit for operation as per manufacturing order</p> <p>P3. Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order</p>
CU2. Check Machine Lubrications	<p>P1. Check gauge of lubricants as per machine manual</p> <p>P2. Verify proper lubrication of machinery as per maintenance schedule</p> <p>P3. Report to in-charge about any deviation.</p>
CU3. Ensure Cleaning of Machine	<p>P1. Check the cleanliness status of machine after completion of each batch as per the instructions given in manual</p> <p>P2. Proper tagging of manufactured products as per manufacturing order.</p> <p>P3. Intimate the area in-charge about completion of each batch as well as for next process as per manufacturing order</p>
CU4. Maintain machine Log-Book	<p>P1. Insert entries in machine log book as per instructions</p> <p>P2. Check log book periodically for effective and smooth running of machine functions</p> <p>P3. Report to in-charge for any unusual response during manufacturing processing</p>
CU5. Follow Machine Operation Procedure	<p>P1. Identify every manufacturing features and notes before start the machine as per manufacturing order</p> <p>P2. Adjust the machine parameters as per product</p>

	<p>manufacturing order, before operating it</p> <p>P3. Perform in process tests according to product manufacturing order and machine operation procedures</p> <p>P4. Intimate to the section in-charge regarding any deviation during process</p>
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Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Explain machine electric input and output system
- K2:** Explain methods of checking electrical input and output.
- K3:** Understand instructional manual of the machine
- K4:** Explain machine mechanical system
- K5:** Define machine PLC/HMI and how it works.
- K6:** Explain different types of lubricants
- K7:** Explain the importance of lubrication for smooth functioning of machine
- K8:** Define machine gauge
- K9:** Describe different methods of checking machine gauge for lubrication
- K10:** Explain the process of machine lubrication
- K11:** Explain the processes of cleanliness of machine
- K12:** Define tags and product name and codes
- K13:** Describe tagging and assigning codes to the products
- K14:** Explain coding system of pharmaceutical products
- K15:** Explain types of log book
- K16:** Explain procedure of maintaining and filling up of log-book properly
- K17:** Define unusual response during processing
- K18:** Describe types and functions of machine
- K19:** Explain different parts of machine
- K20:** Describe the process of machine operation
- K21:** Describe methods of performing process tests correctly
- K22:** Explain possible faults in machine and their repairing
- K23:** Explain the process for maintaining the tools and equipment

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

- Describe types of machine
- Describe critical parts of machine
- Install / changeover of machine parts
- Maintenance and repair of equipment and tools
- Types and uses of equipment
- Preventive and corrective measures for tools and equipment

Tools and Equipment required

The tools and equipment required for this competency standard are given below:

- Logbook
- Machine Manuals

102200846 Apply Work Health and Safety Practices (WHS)

Overview: This unit describes the skills to work with safety and participate in hazard assessment activities, follow emergency procedures and participate OHS practices in process.

Competency Units	Performance Criteria
CU1. Implement safe work practices at work place	<p>P1. Implement relevant rules and procedures of WHS at work place.</p> <p>P2. Comply with duty of care requirements</p> <p>P3. Use personal protective equipment according to safe work practices</p> <p>P4. Contribute to WHS consultative activities</p> <p>P5. Raise WHS issues with relevant personnel</p>
CU2. Participate in hazard assessment activities a work place	<p>P1. Identify hazards or WHS issues in the workplace to relevant personnel</p> <p>P2. Assess and control risks according to own level of responsibility, in line with workplace procedures</p> <p>P3. Report hazards or WHS issues in the workplace to relevant personnel</p> <p>P4. Document risk control actions as required</p>
CU3. Follow emergency procedures at workplace	<p>P1. Report emergencies or incidents promptly to relevant personnel</p> <p>P2. Deal with emergencies in line with own level of responsibility</p> <p>P3. Implement evacuation procedures as required</p>
CU4. Participate in OHS consultative processes	<p>P1. Contribute to workplace meetings, inspections or other consultative activities</p> <p>P2. Raise OHS (Occupational Health and Safety) issues with designated persons in accordance with organizational procedures</p> <p>P3. Take actions to eliminate workplace hazards or to reduce risks</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Outline the WHS rights and responsibilities that apply to own role
- K2:** Explain the term duty of care
- K3:** Describe typical health and safety roles in the workplace
- K4:** List and describe common safety signs and symbols
- K5:** Explain procedures for reporting hazards, risks, incidents and accidents
- K6:** Identify and describe common hazards and major causes of accidents relevant to the workplace
- K7:** Explain what the term risk control means
- K8:** List and describe potential emergency situations and how to respond to them

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

Demonstrate evidences of the Health and safety Processes to avoid any incident.

041700840 Identify and Implement Workplace Policy and Procedures

Overview: This unit describes the skills and knowledge required to develop and implement a workplace policy & procedures and to modify the policy to suit changed circumstances. It applies to individuals with managerial responsibilities who undertake work developing approaches to create, monitor and improve strategies and policies within workplaces and engage with a range of relevant stakeholders and specialists.

Competency Units	Performance Criteria
CU1. Identify workplace policy & procedures	<p>P1. Identify the workplace policy & procedures</p> <p>P2. Apply appropriate strategies that can be used to measure whether your workplace health and safety obligations are being met.</p> <p>P3. Assure the policies are realistic, resources and personnel to implement</p> <p>P4. Implement the policy & procedures that reflects the organizations commitments</p> <p>P5. Ensure the appropriate methods of implementation, outcomes and performance indicators</p>
CU2. Implement workplace policy & procedures	<p>P1. Apply and assign responsibility for recording systems to track continuous improvements in policy & procedures</p> <p>P2. Implement strategies for continuous improvement in effective and efficient information</p>
CU3. Communicate workplace policy & procedures	<p>P1. Communicate procedures to help implement workplace policy</p> <p>P2. Inform those involved in implementing the policy about expected outcomes, activities to be undertaken and assigned responsibilities</p>
CU4. Review the implementation of workplace policy & procedures	<p>P1. Identify the trends that may require remedial actions</p> <p>P2. Record the trends that may require remedial actions.</p> <p>P3. Ensure policy and procedures as required are made for continuous improvement of performance</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Legislation, regulations and codes of practice applicable to the organization
- K2:** internal and external sources of information and organizational policy & procedures
- K3:** Typical barriers to implementing policies and procedures in an organization.

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

Identify evidences of the ability to implement work place policy and procedures. briefly identify work place procedures to avoid incident.

001100852 Communicate at Workplace

Overview: This unit describes the performance outcomes, skills and knowledge required to develop communication skills in the workplace. It covers gathering, conveying and receiving information, along with completing assigned written information under direct supervision.

Competency Units	Performance Criteria
CU1. Communicate within the organization	<p>P1. Communicate within a department</p> <p>P2. Communicate with other departments.</p> <p>P3. Use various media to communicate effectively</p> <p>P4. Communicate orally and written</p>
CU2. Communicate outside the organization	<p>P1. Deal with vendors</p> <p>P2. Deal with clients/customers</p> <p>P3. Interact with other organisations</p> <p>P4. Use various media to communicate effectively</p> <p>P5. Work with people of different cultures / backgrounds</p>
CU3. Communicate effectively in workgroup	<p>P1. Assess the issues to provide relevant suggestion to group members</p> <p>P2. Resolve the issues/ problems /conflicts within the group</p> <p>P3. Arrange group working sessions to increase the level of participation in the group processes</p> <p>P4. Communicate messages to group members clearly to ensure interpretation is valid</p> <p>P5. Communicate style /manner to reflect professional standards/ awareness of appropriate cultural practices</p> <p>P6. Act upon constructive feedback</p>
CU4. Communicate in writing	<p>P1. Identify relevant procedures for written information</p> <p>P2. Use strategies to ensure correct communication in writing. i.e.</p> <ul style="list-style-type: none"> • correct composition • clarity • comprehensiveness • accuracy • appropriateness <p>P3. Draft assigned written information for approval, ensuring it is written within designated timeframes</p>

	<p>P4. Ensure written information meets required standards of style, format and detail</p> <p>P5. Seek assistance / feedback to aid communication skills development</p>
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Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out the tasks covered in this competency standard. This includes the knowledge of:

- K1:** Importance of intra and inter organizational communication
- K2:** Basics of business communication
- K3:** Defining Modes of communication
- K4:** Effective communication in workgroup
- K5:** Communicating through writing
- K6:** The importance of teamwork

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

In your current position, what types of written communication do you use most often? (List them all).

061100858 Perform Computer Application Skills

Overview: This unit describes the skills and knowledge required to use spreadsheet applications, prepare in page documents, develops familiarity with Word, Excel, Access, PowerPoint, email, and computer graphics basics.

It applies to individuals who perform a range of routine tasks in the workplace using a fundamental knowledge of spreadsheets, Microsoft office and computer graphics in under direct supervision or with limited responsibility.

Competency Units	Performance Criteria
CU1. Prepare In-page documents as per required information	<p>P1. Set keyboard preferences according to information requirements</p> <p>P2. Layout Page according to information requirements</p> <p>P3. Toggle between Languages</p> <p>P4. Identify the usage of tool bar</p> <p>P5. Insert Columns as per requirement</p> <p>P6. Print the document</p>
CU2. Prepare Spreadsheets as per required information	<p>P1. Create workbook according to information requirements</p> <p>P2. Insert sheet according to information requirements</p> <p>P3. Enter basic formulae / functions using cell referencing when required</p> <p>P4. Correct formulas when error messages occur</p> <p>P5. Use a range of common tools during spreadsheet development</p> <p>P6. Edit columns and rows within the spreadsheet Filter data</p> <p>P7. Save the spreadsheet to a folder on a storage device</p> <p>P8. Format spreadsheet using formatting features as required</p> <p>P9. Incorporate object and chart in spreadsheet</p> <p>P10. Print spreadsheet</p>
CU3. Use MS Office as per required information	<p>P1. Use Microsoft Word for documentation</p> <p>P2. Use Microsoft Excel for documentation</p> <p>P3. Use Microsoft PowerPoint for presentation</p> <p>P4. Perform OneNote</p> <p>P5. Perform Outlook for emails</p> <p>P6. Perform Publisher applications</p>

<p>CU4. Perform computer graphics in basic applications</p>	<p>P1. Perform graphic fundamentals in basic applications P2. Draw Points and lines to make images P3. Draw Dots in space to make images P4. Draw lightening blot Shapes to make images P5. Enlarge circles and rectangles to block in forms</p>
<p>CU5. Create Email account for communications</p>	<p>P1. Make email account for communications P2. . Compose text of an email message according to organizational guidelines as required P3. Create an automatic signature for the user P4. Attach files to email message where required P5. Send email message P6. Reply to / forward a received message using available features P7. Save an attachment to the relevant folder P8. Save email message using available settings P9. Adjust email accounts to restrict and quarantine possible email security problems</p> <ul style="list-style-type: none"> • Print email message as per requirements

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out the tasks covered in this competency standard. This includes the knowledge of:

- K1:** List basic technical terminology related to reading help files and prompts
- K2:** Explain the effect of formatting and appearance on the readability and usability of spreadsheets
- K3:** Outline log-in procedures relating to accessing a personal computer (PC)
- K4:** Describe the purpose, use and function of spreadsheet applications.
- K5:** Understand **MS Word** to create documents, flyers, publications
- K6:** Understand **MS PowerPoint** to create presentations
- K7:** Understand **MS Excel** to store, organize, and manipulate data
- K8:** Understand **OneNote** to organize data you collect including handwritten notes, drawings, screen captures, audio clips, and more
- K9:** Understand of **Publisher** to create extensive publications, posters, flyers, menus

K10: Understand **Outlook** to manage email and calendars, to do lists, and contacts

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Create spreadsheets
- Customize basic settings
- Format spreadsheets
- Apply basic formulas
- Insert objects and charts in spreadsheets
- Save and print spreadsheets.

041300867 Manage Personal Finances

Overview: This unit of competency describes the outcomes required to manage develop, implement and monitor a personal budget in order to plan regular savings and manage debt effectively.

Competency Units	Performance Criteria
<p>CU1. Develop a personal budget</p>	<p>P1. Calculate current living expenses using available information to prepare a personal budget.</p> <p>P2. Keep a record of all income and expenses for a short period of time to help estimate ongoing expenses.</p> <p>P3. Subtract total expenses from total income to determine a surplus or deficit budget for the specified period.</p> <p>P4. Find reasons for a deficit budget and ways to reduce expenditure identified.</p> <p>P5. Identify ways to increase income</p>
<p>CU2. Develop long term personal budget</p>	<p>P1. Analyze income and expenditure and set long term personal financial goals.</p> <p>P2. Develop a long-term budget based on the outcomes of short-term budgeting.</p> <p>P3. Identify obstacles that might affect the business</p> <p>P4. Formulate a regular savings plan based on budget</p>
<p>CU3. Identify ways to maximize future finances</p>	<p>P1. Determine sources to maximize personal income,</p> <p>P2. Get further education or training to maintain or improve future income.</p> <p>P3. Identify the need for debt to finance living and other expenses,</p> <p>P4. Determine the appropriate levels of debt and repayment.</p> <p>P5. Consolidate existing debt, where possible, to minimize interest costs and fees.</p> <p>P6. Seek professional money management services.</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Explain the abilities to plan and organize to keep records and monitor a personal budget
- K2:** Describe abilities to set and review goals
- K3:** Explain basic financial management and record keeping to enable development and management of a personal budget
- K4:** Describe benefits of financial goal setting and personal budgeting to enable effective management of personal finances
- K5:** Outline numeracy skills to compare income and expenditure

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

Demonstrates competency to provide evidence of the ability to manage personal finances. The evidence should integrate employability skills with workplace tasks and job roles and verify competency is able to be transferred to other circumstances and environments.

091600606 Manufacture Tablets

Overview: This Competency Standard covers the competencies required to apply skills and specific knowledge to perform manufacturing functions by a Pharmaceutical Technician in accordance with the industry's approved guidelines and procedures. This competency covers manufacturing of tablets that includes weighing, milling, sieving, mixing, granulation, compression and coating.

Competency Units	Performance Criteria
CU1. Mix Raw Materials	<p>P1. Check identity of materials against manufacturing order</p> <p>P2. Sieve and add materials as per manufacturing order</p> <p>P3. Start mixing as per manufacturing order</p> <p>P4. Record all necessary entries as per manufacturing order</p> <p>P5. Report to the in-charge about any deviation for quick response</p>
CU2. Perform Slugging (in case of dry granulation)	<p>P1. Install required sieve as per manufacturing order in compactor granulator</p> <p>P2. Shift materials in compactor granulator as per manufacturing order</p> <p>P3. Start granulator and adjust rollers for proper flack size as per manufacturing order</p> <p>P4. Collect dry granules after completion of process as per manufacturing order</p> <p>P5. Report to the in-charge about any deviation for quick response</p>
CU3. Perform wet mixing	<p>P1. Prepare binder solution as per manufacturing order</p> <p>P2. Mix binder solution with powder mixture to form wet mass as per manufacturing order</p> <p>P3. Start mixing as per specific mixing time of batch as per manufacturing order</p> <p>P4. Check end point of wet mixing properly and report to the in-charge about any deviation</p>
CU4. Perform wet granulation	<p>P1. Install required mesh size in the wet granulator as per manufacturing order</p> <p>P2. Shift and pass the wet mass through granulator</p>

	<p>P3. Report to the in-charge about any deviation</p>
<p>CU5. Collect Wet Granules and Dry</p>	<p>P1. Collect wet granules for drying as per specifications given in manufacturing order</p> <p>P2. Transfer wet granulates reliably for completion of drying process as per manufacturing order</p> <p>P3. Adjust temperature of dryer as per specifications for completion of drying process</p> <p>P4. Determine end point of drying process and record any deviation faced during the whole procedure</p>
<p>CU6. Perform Dry Granulation</p>	<p>P1. Collect dry granules/flacks (in case of slug)</p> <p>P2. Shift dry granules/flacks for required sizing as per manufacturing order</p> <p>P3. Intimate section in-charge for end point confirmation of granulation.</p>
<p>CU7. Perform Sieving (Mesh)</p>	<p>P1. Pass materials from required sieve size as per manufacturing order</p> <p>P2. Record all necessary entries as per requirements of Manufacturing order</p> <p>P3. Report to the in-charge about any deviation</p>
<p>CU8. Perform Final Mixing</p>	<p>P1. Identity materials for final mixing against manufacturing order</p> <p>P2. Add materials as per manufacturing order</p> <p>P3. Perform final mixing of batch material as per manufacturing order</p> <p>P4. Enter all necessary entries as per manufacturing order</p> <p>P5. Intimate section in-charge about final mixing for next process as per manufacturing order</p>
<p>CU9. Shift Material to Compression Room</p>	<p>P1. Receive approval from concerned section in-charge.</p> <p>P2. Identify trolley for shifting material to compression room for next process</p> <p>P3. Perform weight and record of received materials as per specifications</p>

	<p>P4. Place materials on pallets using appropriate and safe methods. Report any deviations, if any, during shifting process to avoid loss</p>
<p>CU10. Start Compression Machine</p>	<p>P1. Adjust machine as per manufacturing order using relevant controls</p> <p>P2. Add bulk batch materials in hopper</p> <p>P3. Start and adjust weight and hardness as per manufacturing order</p> <p>P4. Perform required in-process tests.</p> <p>P5. Operate machine as per job requirements and report deviation, if observed</p>
<p>CU11. Check Weight Variation of Tablets</p>	<p>P1. Check calibration status of balance using appropriate method</p> <p>P2. Adjust balance using appropriate techniques</p> <p>P3. Take tablets for measuring weight variation test as per manufacturing order</p> <p>P4. Note in process reading as per procedure in manufacturing order</p> <p>P5. Report any deviation to in- charge</p>
<p>CU12. Shift compressed tablets for coating or sorting</p>	<p>P1. Shift core tablets after release approval from quality assurance department</p> <p>P2. De-dust tablets using relevant tools and appropriate methods</p> <p>P3. Prepare coating solution using specified techniques</p> <p>P4. Load core tablets in coating pan as per manufacturing order</p> <p>P5. Adjust coating machine parameters as per specification.</p> <p>P6. Start coating process and check weight gain after specified interval</p> <p>P7. Finish coating process, when required weight is achieved</p> <p>P8. Polish coated tablets using specified procedure</p> <p>P9. Report any deviation.</p>

Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Explain sieve process
- K2:** Describe different types of sieves
- K3:** Know about Deviation process
- K4:** Define manufacturing orders
- K5:** Explain mixing methods and concerns for correct and safe mixing
- K6:** Define granulators
- K7:** Define pressure of rollers
- K8:** Describe deviation process
- K9:** Describe procedure for sieve in compactor granulator
- K10:** Describe types of wet mixing solution (Aqueous & organic)
- K11:** Describe techniques for mixing
- K12:** Explain check end point of wet mixing properly
- K13:** Describe different types of granules
- K14:** Explain types of granulators and deviation in dry granulation process
- K15:** Explain types of dryers
- K16:** Define thermostat
- K17:** Explain reasons and procedure for adjusting temperature of dryer
- K18:** Explain procedure of sieving (Mesh)
- K19:** Define processes of dry granulation
- K20:** Describe process of adding materials for final mixing
- K21:** Explain different types of pallets
- K22:** Explain safety concerns while shifting materials to compression room
- K23:** Define compression machine
- K24:** Explain tablet weighing technique
- K25:** Explain procedure of checking calibration status of balance
- K26:** Explain coating solution process

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

- Adjust wet granulator
- Adjust dry granulator
- Set dryer parameters
- Adjust weight variation
- Check hardness and thickness of tablets
- Set coating parameters
- Demonstrate compression machine
- Installation procedure for sieve in compactor granulator
- Sieve process

Tools and Equipment required

The tools and equipment required for this competency standard are given below:

- Stainless-steel high-speed mixing machine/ groove mixer
- Mixer machine for solution preparation
- Stainless steel wet granulation machine
- Stainless steel blender
- Compactor granulator
- Wet mixer (Grail/sigma mixer)
- Oscillator granulator
- Stainless-steel high-speed mixing machine/ groove mixer
- Mixer machine for solution preparation
- Stainless steel wet granulation machine
- Stainless steel blender
- Compactor granulator
- Wet mixer (Grail/sigma mixer)
- Oscillator granulator
- Stainless-steel high-speed mixing machine/ groove mixer

091600607 Manufacture Capsules and Dry Suspension

Overview: This Competency Standard covers the competencies required to apply skills and specific knowledge to perform manufacturing functions by a Pharmaceutical Technician in accordance with the industry approved guidelines and procedures. The trainee will be involved to perform weighing, sieving, mixing, granulation, encapsulation and polishing. This competency also covers manufacturing of dry suspension that includes weighing, sieving, mixing, bottle filling and sealing.

Competency Units	Performance Criteria
CU1. Mix Raw Materials	<p>P1. Check identity of materials against manufacturing order</p> <p>P2. Sieve and add materials as per manufacturing order</p> <p>P3. Start mixing as per manufacturing order</p> <p>P4. Record all necessary entries as per manufacturing order</p> <p>P5. Report to the in-charge about any deviation for quick response</p>
CU2. Perform wet granulation	<p>P1. Install required mesh size in the wet granulator as per manufacturing order</p> <p>P2. Shift and pass the wet mass through granulator</p> <p>P3. Report to the in-charge about any deviation</p>
CU3. Collect Wet Granules and Dry (If required)	<p>P1. Collect wet granules for drying as per specifications given in manufacturing order</p> <p>P2. Transfer wet granulates reliably for completion of drying process as per manufacturing order</p> <p>P3. Adjust temperature of dryer as per specifications for completion of drying process</p> <p>P4. Determine end point of drying process and record any deviation faced during the whole procedure</p>
CU4. Perform Dry Granulation (If required)	<p>P1. Collect dry granules/flacks (in case of slug)</p> <p>P2. Shift dry granules/flacks for required sizing as per manufacturing order</p> <p>P3. Intimate section in-charge for end point confirmation of granulation.</p>

<p>CU5. Perform Final Mixing</p>	<p>P1. Identity materials for final mixing against Manufacturing Order</p> <p>P2. Add materials as per manufacturing order</p> <p>P3. Perform final mixing of batch material as per manufacturing order</p> <p>P4. Enter all necessary entries as per manufacturing order</p> <p>P5. Intimate section in-charge about final mixing for next process as per manufacturing order</p>
<p>CU6. Shift material in encapsulation room for filling</p>	<p>P1. Shift materials to encapsulation area after release approval from quality assurance department</p> <p>P2. Adjust machine as per manufacturing order</p> <p>P3. Add materials in hopper as per specifications</p> <p>P4. Start encapsulation machine</p> <p>P5. Perform required in-process tests</p> <p>P6. Adjust weight and locking as per manufacturing order</p> <p>P7. Make polish and sorting of filled capsules as per process</p> <p>P8. Report any deviation to in-charge</p>
<p>CU7. Start bottle blowing & filling (dry suspension)</p>	<p>P1. Check approval from Quality Assurance before filling of bottles</p> <p>P2. Transfer empty bottles to filling line and place it on the turn table</p> <p>P3. Adjust bottle blowing according to the specific bottle size and start blowing process</p> <p>P4. Adjust the weight of individual nozzle according to manufacturing order</p>
<p>CU8. Capping, optical checking & labeling of bottles</p>	<p>P1. Adjust capping and sealing machine of the lines according to the speed of filling</p> <p>P2. Check individual bottle optically in different background for all types of particles</p> <p>P3. Adjust labeling machine according to the speed of line</p> <p>P4. Perform all required in- process checks as per manufacturing order</p> <p>P5. Report any deviation from the standards to section in-</p>

	charge
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Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Define mixing methods and concerns for correct and safe mixing
- K2:** Define methods for correct entries
- K3:** Define types of granulation techniques
- K4:** Elaborate problems faced during granulation process
- K5:** Define thermostat
- K6:** Explain processes of dry granulation
- K7:** Explain process of adding materials for final mixing
- K8:** Describe types of hoppers
- K9:** Describe start encapsulation machine
- K10:** Define types of capsule polishing machines
- K11:** Describe physical parameters of capping & leakage
- K12:** Define Optical checking.
- K13:** Define Label pasting.
- K14:** Know awareness about process protocol
- K15:** Label solutions, define their characteristics, and their usages at the pharmaceutical manufacturing

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

- Adjust wet granulator
- Adjust dry granulator
- Set dryer parameters
- Adjust weight variation

Tools and Equipment required

The tools and equipment required for this competency standard are given below:

- Stainless-steel high-speed mixing machine/ groove mixer
- Mixer machine for solution preparation
- Stainless steel wet granulation machine
- Stainless steel blender
- Stainless-steel high-speed mixing machine/ groove mixer
- Mixer machine for solution preparation
- Stainless steel wet granulation machine
- Stainless steel blender
- Stainless-steel high-speed mixing machine/ groove mixer
- Mixer machine for solution preparation
- Wet mixer (Grail/sigma mixer
- Trays/bin in case (Fluidize bed dryer)
- Fitz Mill
- Containers
- Capsules filling machine
- Bottle blower
- Bottle filling machine
- Capping, Sealing and labeling machine
- Containers
- Capsules filling machine
- Bottle blower
- Bottle filling machine

091600608 Manufacture Liquid Dosages

Overview: This Competency Standard covers the competencies required to apply skills and specific knowledge to perform manufacturing of syrup, suspension as per manufacturing order, general housekeeping and maintenance of tools/equipment.

Competency Units	Performance Criteria
CU1. Shift the Raw Materials	<p>P1. Transfer batch raw materials to liquid section</p> <p>P2. Check the materials one by one according to the manufacturing order in the section again prior to mixing</p> <p>P3. Segregate each material according to mixing order</p> <p>P4. Report any deviation to section in charge</p>
CU2. Prepare syrup base	<p>P1. Transfer specified volume of purified water to steam jacketed tank</p> <p>P2. Start heating up to the required temperature</p> <p>P3. Add preservative(s) as per specification</p> <p>P4. Add sucrose as per specification and continue heating to required temperature</p> <p>P5. Continue mixing until clear base is formed.</p> <p>P6. Check the cleaning status of filtration assembly.</p> <p>P7. Filter and transfer the base to the main Mixing tank after cooling.</p> <p>P8. Report Any deviation from the standards to section in-charge.</p>
CU3. Dissolve/ Soak materials in purified water according to procedure	<p>P1. Transfer specified volume of purified water to different manufacturing tanks.</p> <p>P2. Soak materials in case of suspension and dissolve material in case of solution separately as per manufacturing order</p> <p>P3. Report any deviation from the standards to section in-charge</p>
CU4. Manufacture syrup and suspension	<p>P1. Check the temperature of syrup base in the main mixing tank</p> <p>P2. Add the materials one by one to the main mixing tank. In case of syrup the already dissolved material/s is also added</p> <p>P3. Pass suspension slurry through homogenizer and add it to</p>

	<p>main mixing tank</p> <p>P4. Make up and record bulk volume of syrup/suspension in main mixing tank</p> <p>P5. Transfer syrup through filtration assembly according to specification and suspension directly to storage tank (through homogenizer if required)</p> <p>P6. Start slow mixer in storage tank in case of suspension</p> <p>P7. Intimate section in-charge about process completion</p> <p>P8. Seal storage tank till release from Quality Assurance after sampling</p> <p>P9. Any deviation from the standards must be reported to section in-charge</p>
<p>CU5. Start bottle blowing & filling</p>	<p>P1. Check approval of Quality Assurance before filling of bottles</p> <p>P2. Transfer empty bottles to filling line and place it on the turn table</p> <p>P3. Adjust bottle blowing according to the specific bottle size and start blowing process</p> <p>P4. Adjust the Volume of individual nozzle according to manufacturing order</p>
<p>CU6. Capping, optical checking & labeling of bottles</p>	<p>P1. Adjust capping and sealing machine of the lines according to the speed of filling</p> <p>P2. Check individual bottle optically in different background for all types of particles</p> <p>P3. Adjust labeling machine according to the speed of line</p> <p>P4. Perform all required in- process checks as per manufacturing order</p> <p>P5. Report any deviation from the standards to section in-charge</p>

Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Define product name, batch number & strength
- K2:** Describe mixing order awareness
- K3:** Describe different types of material
- K4:** Explain types of tanks
- K5:** Describe heating process
- K6:** Define color and solubility of material
- K7:** Define preservative(s) and sucrose
- K8:** Explain types of filtration assembly and technique.
- K9:** Define syrup and suspension
- K10:** Describe homogenizer adjustment and slurry particle size
- K11:** Explain volume making and calibration of mixing tank.
- K12:** Describe types of filtration assembly and technique
- K13:** Explain types of transfer pump involved in the process
- K14:** Define mixing speed of slow mixer
- K15:** Explain types of filling line.
- K16:** Define process of blowing bottles
- K17:** Explain types of nozzles
- K18:** Describe volume limits for various packaging
- K19:** Describe method of adjusting volume of each nozzle
- K20:** Know about hygienic measures (GMP) for pharmaceutical production

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

- Operate purified water plant
- How to make final volume
- What is soaking
- Mixing order awareness
- Types of transfer equipment
- How to adjust filling volume?

Tools and Equipment required

The tools and equipment required for this competency standard are given below:

- Batch shifting trolley
- Reverse osmosis plant
- Stainless steel jacketed tank
- Mixers
- Transfer pump
- Filtration assembly
- Colloidal mill
- Silver son mixer
- Optical checking assembly
- Capping, Sealing and labeling machine

091600609 Perform Packaging as per Manufacturing Order

Overview: This Competency Standard covers the competencies required to apply skills and knowledge to perform packing of manufacturing products as per industry's approved guidelines and procedures. Trainees will be expected to perform packaging of tablets, capsules, bottles, handling for warehouse storage & shipping transport and general housekeeping and maintenance of equipment. Your underpinning knowledge is sufficient to provide you the basic for your work.

Competency Units	Performance Criteria
CU1. Receive packing materials for product (tablets, capsules & syrups/suspensions)	<p>P1. Check and receive printed/ unprinted aluminum Foil Roll, Poly Vinyl Chloride (PVC) Roll, bottles, caps, vials, rubber stoppers, flip off seals, ampoules, unit carton, spoons, leaflets, cups, master cartons, labels as per packing order.</p> <p>P2. Maintain the temperature and humidity of workplace as per requirements of specifications of manufactured product</p> <p>P3. Check the Batch Number, manufacturing and expiry date against each labeled packing as per manufacturing order</p> <p>P4. Ensure all relevant entries manually or electronically as per specifications given in manufacturing order</p> <p>P5. Intimate to section in-charge after completion of task</p>
CU2. Make strip/blister packing	<p>P1. Prepare label area, machines & containers for strip packing correctly as per specifications given in the Packing Order</p> <p>P2. Check & sign the "Ready Tag" attached to the machine and make necessary entries in the log book.</p> <p>P3. Receive approval from section in-charge before start packing of manufactured products</p> <p>P4. Start strip/blistering operation and perform the following checks:</p> <p>P5. Set Batch No., Manufacturing & expiry dates</p> <p>P6. Count of unit dose per blister/strip</p> <p>P7. Alignment of blister/ strip</p> <p>P8. Check release label on the buckets /drums.</p> <p>P9. Intimate section in-charge to take empty blisters/strips for</p>

	<p>leak-test.</p> <p>P10. Start the Blistering/stripping Operation, only after passing the Leak Test for empty & filled blisters/strips.</p> <p>P11. Check the completion of blistering/stripping process and shift the blisters/strips to packing hall for packaging as per specifications</p>
CU3. Perform Over printing	<p>P1. Remove all printed packaging material like Labels, unit cartons, Blisters/strips etc. of the previous product</p> <p>P2. Check that the correct packaging material as per Packaging order for printing</p> <p>P3. Check Batch No. expiry, manufacturing date, pack size against packaging order for printing on the carton or labels</p> <p>P4. Perform in process checks to avoid any wastages</p>
CU4. Perform aluminum blister foil packaging, strip packaging/ bottle packaging	<p>P1. Remove all printed packaging material like labels, unit cartons, Blisters/strips etc. of the previous product</p> <p>P2. Check correct packaging material as per packing order is received for concerned batch</p> <p>P3. Received blisters/strips, bottles, printed cartons, printed labels of product</p> <p>P4. Check Batch. No. manufacturing date, expiry and pack size</p> <p>P5. Take approval for product to be packed</p> <p>P6. Check labels, cartons blister/blisters etc.</p> <p>P7. for proper printing</p> <p>P8. Remanufacturing ordered defective printed materials immediately</p> <p>P9. Bring the cartons, Labels, Blisters for sorting in a Tray & Label it as "<u>FOR SORTING</u>"</p> <p>P10. Collect all the rejected cartons, Labels, Blisters</p> <p>P11. in a tray, and label it as "<u>REJECTED</u>"</p> <p>P12. Collect Cartons, Labels, Blisters/strips in a separate tray and label it as "<u>READY FOR USE</u>"</p> <p>P13. Shift only ready for use Cartons, Labels for packaging on belt</p> <p>P14. Take blisters/strips, bottle, ampoule, and vial according to</p>

	the unit carton and insert pack.
CU5. Make tertiary packaging for bulk handling for warehouse storage & shipping/transport	<p>P1. Place required number of packs in the master carton as per packing order.</p> <p>P2. Seal each master carton properly with sealing carton Tape.</p> <p>P3. Check each master carton label before pasting it on each sealed master carton for its product name, Manufacturing date, expiry date, master cartons No., quantity of units & packaging date</p> <p>P4. Arrange each outer carton properly on pallet</p> <p>P5. Deliver batch to finish goods store after release from Quality Assurance</p>

Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Explain types of packing material
- K2:** Elaborate batch number, manufacturing and expiry date correctly as per packaging order
- K3:** Explain specific requirements of temperature and humidity of workplace for each product
- K4:** Describe enlisting specifications and data.
- K5:** Define leak test protocols
- K6:** Describe types of packaging machine
- K7:** Describe method of checking and signing the ready tag
- K8:** Describe method of blistering/stripping operation
- K9:** Describe types of printing machines
- K10:** Describe proper and safe methods of arranging carton on pallet
- K11:** Describe method of sealing carton using carton tape

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Adjust batch No. expiry on printing and blister machine
- Sorting procedure
- Labeling information

Tools and Equipment required

The tools and equipment required for this competency standard are given below:

- Containers
- Blister/strip machine
- Printing Machine
- Tertiary packing machine
- Bottle capping and sealing machine

102200848 Contribute to Work Related Health and Safety (WHS) Initiatives

Overview: This unit describes the skills and knowledge required to manage the identification, review, development, implementation and evaluation of effective participation and consultation processes as an integral part of managing work health and safety (WHS).

Competency Units	Performance Criteria
CU1. Contribute to initiate work-related health and safety measures	<p>P1. compile database on work-related health and safety</p> <p>P2. Identify measures that address legal obligations.</p> <p>P3. Consult with individuals/ parties to formulate measures and initiatives</p> <p>P4. Consult with individuals/parties to identify factors impacting on work-related health and safety</p> <p>P5. Participate in consultative meetings.</p>
CU2. Contribute to establish work-related health and safety measures	<p>P1. Assist in planning of work-related health and safety measures</p> <p>P2. Contribute to the development of work-related health and safety measures</p> <p>P3. Identify to implement work-related health and safety measures i.e.</p> <ul style="list-style-type: none"> • resourcing requirements, • timelines • responsibilities <p>P4. Assist to implement work-related health and safety measures and initiatives i.e.</p> <ul style="list-style-type: none"> • scheduling • liaison • administering resources • communication
CU3. Contribute to ensure legal requirements of WHS measures	<p>P1. Identify WHS legal requirements</p> <p>P2. Apply knowledge of all aspects of WHS measures to</p> <ul style="list-style-type: none"> • Consultation • workplace policies • participation processes <p>P3. Ensure, WHS measures are in accordance with legal requirements</p>

<p>CU4. Contribute to review WHS measures</p>	<p>P1. Develop effective practices to review work-related health and safety measures</p> <p>P2. Assist individuals and parties related to WHS measures in following activities</p> <ul style="list-style-type: none"> • preparing reports • communicating review • evaluating outcomes
<p>CU5. Evaluate the organization's WHS system</p>	<p>P1. Assess ongoing compliance with OHS (Occupational Health and safety)</p> <p>P2. Take feedback from concerned persons regarding WHS measures.</p> <p>P3. Assess the overall effectiveness of WHS management practices</p> <p>P4. Assist the development process of WHS measures in following ways</p> <ul style="list-style-type: none"> • Suggest amendments • Document amendments • Implement amendments <p>P5. Take feedback from concerned persons regarding WHS measures.</p> <p>P6. Communicate improvements in WHS Measures</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Explain the application of relevant mandatory health monitoring, including biological monitoring, to help secure work health and safety
- K2:** Explain the difference between work-related health and safety measures and initiatives designed to meet specific legislative requirements and obligations, and those designed to support non-statutory health promotion programs, and give examples of each
- K3:** List factors that impact on work-related health and safety and their potential effects
- K4:** Identify internal and external sources of WHS information and data, and how to access them

- K5:** Outline organizational WHS and other relevant policies, procedures, processes and systems, including human resources
- K6:** Summarize relevant WHS legislation, other legislation (such as privacy and workers compensation) and common law rights and duties specific to work-related health and safety measures and initiatives
- K7:** Describe work-related health and safety measures and initiatives that either address specific legislative requirements and obligations, or support non-statutory health prevention programs, including:
- The factors impacting on worker health and safety that they address
 - Effectiveness
 - Costs and benefits
 - Criteria for decisions regarding their implementation in a specific workplace
 - How they should be implemented.

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

A person who demonstrates competency in this unit must be able to provide evidence of the ability to contribute work-related health and safety measures and initiatives. The evidence should integrate employability skills with workplace tasks and job roles and verify competency is able to be transferred to other circumstances and environments.

041700841 Comply with Workplace Policy and Procedures

Overview: This unit describes the skills and knowledge required to implement a workplace policy & procedures and to modify the policy to suit changed circumstances. It applies to individuals with managerial responsibilities who undertake work developing approaches to create, monitor and improve strategies and policies within workplaces and engage with a range of relevant stakeholders and specialists.

Competency Units	Performance Criteria
CU1. Manage work timeframes	<p>P1. Complete work tasks within deadlines in according to order of priority</p> <p>P2. Supervisors are informed of any delays in work times or projects</p>
CU2. Manage to convene meeting	<p>P1. Develop agenda in line with meeting purpose</p> <p>P2. Select participants and notify them accordingly</p> <p>P3. Carryout meeting arrangements according to the time</p> <p>P4. Record the minutes of the meeting</p>
CU3. Decision making at workplace	<p>P1. Identify the problem, challenge or opportunity</p> <p>P2. Generate an array of possible solutions or responses</p> <p>P3. Evaluate the costs and benefits associated with each option</p> <p>P4. Assess the impact of the decision and modify the course of action as needed</p>
CU4. Set and meet own work priorities at instant	<p>P1. Take initiative to prioritize and facilitate competing demands to achieve organizational goals and objectives</p> <p>P2. Use technology efficiently and effectively to manage work priorities and commitments</p> <p>P3. Maintain appropriate work-life balance</p>
CU5. Develop and maintain professional competence	<p>P1. Assess personal knowledge and skills against competency</p> <p>P2. Participate in networks to enhance personal knowledge, skills and work relationships</p> <p>P3. Seek feedback from employees, clients and colleagues to develop and improve competence</p>

CU6. Follow and implement work safety requirements	P1. Identify and report emergency incidents P2. Practice organizational policy and procedures for responding to emergency incidents P3. Identify and implement workplace procedures and work instructions for controlling risks
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Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Healthy work life balance
- K2:** Meeting terminologies, structures and arrangements
- K3:** Relevant organizational procedures and policies regarding meetings, chairing and minutes.
- K4:** Barriers to implement policies and procedures in an organization and possible strategies to address them.

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

A person who demonstrates competency in this unit must be able to provide evidence of the ability to understand workplace policy and procedures. The evidence should integrate employability skills with workplace tasks and job roles and verify competency is able to be transferred to other circumstances and environments

001100853 Perform Advanced Communication

Overview: This unit describes the performance outcomes, skills and knowledge required to develop communication skills used professionally. It covers plan and organise work and conduct trainings at workplace, along with demonstrating professional skills independently.

Competency Units	Performance Criteria
CU1. Demonstrate professional skills	<p>P1. Use different modes of communication to communicate</p> <ul style="list-style-type: none"> • Speaking • Reading • Writing • Listening • Presentation • visual representation etc. <p>P2. Develop CV Skills according requirements</p> <p>P3. Upgrade professional skills by attending trainings, webinars, conferences etc.</p> <p>P4. Perform Continuous professional development as required at workplace</p> <p>P5. Develop interview skills</p>
CU2. Plan and Organize work	<p>P1. Identify task requirements.</p> <p>P2. Plan steps to complete tasks.</p> <p>P3. Review planning and organizing process.</p> <p>P4. Organize work.</p>
CU3. Provide trainings at workplace	<p>P1. Assess the need for training</p> <p>P2. Prepare trainees for the learning experience</p> <p>P3. Present training session</p> <p>P4. Support trainees in managing their own learning</p> <p>P5. Facilitate group learning</p> <p>P6. Provide opportunity for practice</p> <p>P7. Provide feedback on progress on trainees</p> <p>P8. Review delivery experience</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out the tasks covered in this competency standard. This includes the knowledge of:

- K1:** Explaining the training skills
- K2:** Identification of the professional skills
- K3:** Describing the advanced language skills
- K4:** Understanding of the assessment and trainees feedback methods
- K5:** Direct and indirect communication methods
- K6:** Explaining the need of the training type at the work place

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Job sheet
- Office emails and coordination reports
- Feedback proforma

061100858 Develop Advance Computer Application Skills

Overview: This unit provides an overview of Microsoft Office programs to create personal, academic and business documents following current professional and/or industry standards, i.e. Data Entry, Power Point Presentation and managing data base and graphics for Design
It applies to individuals employed in a range of work environments who need to be able to present a set range of data in a simple and direct forms

Competency Units	Performance Criteria
<p>CU1. Manage Information System to complete a task</p>	<p>P1. Perform Data Entry in MS office</p> <p>P2. Manage File/folder in MS office</p> <p>P3. Perform Scanning of document</p> <p>P4. Maintain Office Record in drives</p> <p>P5. Perform Printing of document</p> <p>P6. Search required Files/Folders</p> <p>P7. Convert Files in required format.</p> <p>P8. Manage sizes of Files/Folders</p> <ul style="list-style-type: none"> • Compress • Zip /unzip
<p>CU2. Prepare Presentation using computers</p>	<p>P1. Prepare presentation as per requirements, i.e.</p> <ul style="list-style-type: none"> • Open blank presentation and add text / graphics • Create a simple design for a presentation • Apply existing styles within a presentation • Use presentation template and slides to create a presentation • Use various tools to improve the look of the presentation • Save presentation to the appropriate storage device and folder with required name <p>P2. Customize basic settings to meet user requirements</p> <p>P3. Format presentation as require</p> <ul style="list-style-type: none"> • Develop organizational charts • Add objects and manipulate to meet presentation purposes • Modify slide layout, including text and colours, to meet presentation requirements • Save presentation in another format • Save to storage device and close presentation

	<p>P4. Add slide show effect into presentation as required to enhance the presentation</p> <ul style="list-style-type: none"> • Incorporate pre-set Animation • Apply Multimedia effects • Record Narration • Apply hyperlink • Apply video • Rehearse Timings • Test presentation for overall effect <p>P5. Print the presentation</p> <ul style="list-style-type: none"> • Select appropriate print format for presentation • Select preferred slide orientation • Add notes and slide numbers • Preview slides and run spell check before presentation • Print selected slides and submit presentation to appropriate person for feedback <p>P6. Practice verbal presentation</p> <p>P7. Practice presentation through AV Aids</p>
<p>CU3. Use Microsoft Access to manage database</p>	<p>P1. Collect the data using a standard data base package.</p> <p>P2. Start access to manage database .i.e.</p> <ul style="list-style-type: none"> • identify problem statement of Data • Develop a table with fields /attributes according to database usage/ user requirements • Create a primary key and establish an index for each table • Modify table layout and field attributes as required • Create a relationship between the two tables • Add data in a table according to information requirements • Add records as required • delete records as required • Save database to storage area • close down database to storage area • Apply criteria in the following Query • SQL view of Query

	<ul style="list-style-type: none"> • Wildcards of query • Query Criteria <p>P3. Customize basic settings:</p> <ul style="list-style-type: none"> • Adjust page layout to meet user requirements • Open and view different toolbars • Format font as appropriate for the purpose of the database entries • Create reports • Design reports to present data in a logical sequence • Modify reports to include or exclude additional requirements • Distribute reports to appropriate person in a suitable format <p>P4. Create forms</p> <ul style="list-style-type: none"> • Use a wizard to create a simple form • Open existing database and modify records through a simple form • Rearrange objects within the form to accommodate information requirements
<p>CU4. Develop graphics for Design</p>	<p>P1. Develop graphic design concepts based on a thorough understanding of the communication need</p> <p>P2. Use design techniques confidently to produce designs</p> <p>P3. Integrate design tools skillfully to produce designs</p> <p>P4. Evaluate the success of completed designs to meet objectives</p> <p>P5. evaluate feedback from client / peers</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out the tasks covered in this competency standard. This includes the knowledge of:

- K1:** List basic technical terminology to read help files and prompts
- K2:** Outline the different types of formal and informal presentations
- K3:** Explain Power point presentation

- K4:** Segregation of Data
- K5:** Define the relation among data
- K6:** Define criteria in the query
- K7:** Creates and modify reports and forms.
- K8:** Outline basic database design principles
- K9:** Current graphic design software
- K10:** Discuss features of current and emerging technologies used in graphic design practice and the options they present for effective graphic design solution

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Design and develop a simple database using a standard database package
- Create, format and prepare presentations for distribution and display
- Customize basic settings
- Add slide show effects.
- Generate employment report from given data by using Microsoft Access.

041300869 Manage Human Resource Services

Overview: This unit describes the skills and knowledge required to plan, manage and evaluate delivery of human resource services, integrating business ethics. It applies to individuals with responsibility for coordinating a range of human resource services across an organization. They may have staff reporting to them.

Competency Units	Performance Criteria
<p>CU1. Determine strategies for delivery of human resource services</p>	<p>P1. Analyze business strategy and operational plans to determine human resource requirements</p> <p>P2. Review external business environment that likely impact on organization's human resource requirements</p> <p>P3. Consult line and senior managers to identify human resource needs in their areas</p> <p>P4. Review organization's requirements for diversity in the workforce</p> <p>P5. Deliver human resource services that comply with business goals</p> <p>P6. Develop strategic action plan for delivery of human resource services</p> <p>P7. Develop roles and responsibilities of human resource team</p> <p>P8. Develop quality assurance policy</p>
<p>CU2. Manage the delivery of human resource services</p>	<p>P1. Communicate human resource strategies and services to internal and external stakeholders</p> <p>P2. Develop and negotiate service agreements between</p> <ul style="list-style-type: none"> • The human resource team, • Service providers • Client groups <p>P3. Document service specifications, performance standards and timeframes</p> <p>P4. Document /communicate service</p> <ul style="list-style-type: none"> • Specifications, • Performance standards • Timeframes <p>P5. Monitor Quality assurance processes</p> <p>P6. Ensure that services are delivered by appropriate providers, according to service agreements and operational plans</p> <p>P7. Identify underperformance of human resource team or</p>

	service providers
CU3. Evaluate human resource service delivery	<p>P1. Establish Management information system for human resource services</p> <p>P2. Conduct survey to determine level of satisfaction</p> <p>P3. Analyze feedback of survey</p> <p>P4. Recommend changes to service delivery</p> <p>P5. Support agreed change processes across the organization</p>
CU4. Manage integration of business ethics in human resource practices	<p>P1. Ensure ethics in personal behavior</p> <p>P2. Ensure code of conduct is observed across the organization,</p> <p>P3. Observe confidentiality requirements in dealing with all human resource information</p> <p>P4. Deal promptly with unethical behavior</p> <p>P5. Ensure all persons responsible for human resource functions understand requirements regarding their ethical behavior</p>

Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Identify the key provisions of legal and compliance requirements that apply to managing human resources
- K2:** Summarize the organization's code of conduct
- K3:** Explain human resource strategies and planning processes and their relationship to business and operational plans
- K4:** Describe performance and contract management
- K5:** Explain how feedback is used to modify the delivery of human resources.

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

A person who demonstrates competency in this unit must be able to provide evidence of the ability to manage human resource services. The evidence should integrate employability skills with workplace tasks and job roles and verify competency is able to be transferred to other circumstances and environments.

Performance requirements

This competency is to be assessed using standard and authorized work practices, safety requirements and environmental constraints. Demonstrated evidence is required of the ability to:

- Plan and manage human resource delivery within legislative, organizational and business ethics frameworks
- Communicate effectively with a range of senior personnel
- Identify and arrange training support where appropriate
- Calculate human resource return on investment within the organization.

041300860 Develop Entrepreneurial Skills

Overview: This Competency Standard identifies the competencies required to develop entrepreneurial skills, in accordance with the organization's approved guidelines and procedures. You will be expected to develop a business plan, collect information regarding funding sources, develop a marketing plan and develop basic business communication skills. Your underpinning knowledge regarding entrepreneurial skills will be sufficient to provide you the basis for your work.

Competency Units	Performance Criteria
CU1. Develop a business plan	<p>P1. Conduct a market survey to collect following information</p> <ul style="list-style-type: none"> • Customer /demand • Tools, equipment, machinery and furniture with rates • Raw material • Supplier • Credit / funding sources • Marketing strategy • Market trends • Overall expenses • Profit margin <p>P2. Select the best option in terms of cost, service, quality, sales, profit margin, overall expenses</p> <p>P3. Compile the information collected through the market survey, in the business plan format</p>
CU2. Collect information regarding funding sources	<p>P1. Identify the available funding sources based on their terms and conditions, maximum loan limit, payback time, interest rate</p> <p>P2. Choose the best available option according to investment requirement</p> <p>P3. Prepare documents according to the loan agreement requirement</p> <p>P4. Include the information of funding sources in the business plan</p>
CU3. Develop a marketing plan	<p>P1. Make a marketing plan for the business including product, price, placement, promotion, people, packaging and positioning</p> <p>P2. Include the information of marketing plan in the business plan</p>

<p>CU4. Develop basic business communication skills</p>	<p>P1. Communicate with internal customers e.g.: labor, partners and external customers e.g.: suppliers, customers etc., using effective communication skills</p> <p>P2. Use different modes of communication to communicate internally and externally e.g.: presentation, speaking, writing, listening, visual representation, reading etc.</p> <p>P3. Use specific business terms used in the market</p>
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Knowledge and Understanding

The candidate must be able to demonstrate underpinning knowledge and understanding required to carry out tasks covered in this competency standard. This includes the knowledge of:

- K1:** Explain the 7ps of marketing including product, price, placement, promotion, people, packaging and positioning
- K2:** Describe 7Cs of business communication
- K3:** Define different modes of communication and their application in the industry
- K4:** Enlist specific business terms used in the industry
- K5:** Enlist the available funding sources
- K6:** Explain how to get loan to start a new business
- K7:** Explain market survey and its tools e.g. questionnaire, interview, observation etc.
- K8:** Describe the market trends for specific product offering
- K9:** State the main elements of business plan
- K10:** Explain how to fill the business plan format

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

A person who demonstrates competency in this unit must be able to provide evidence of the ability to develop Entrepreneurial Skills.

Performance requirements

- Conduct market survey and formulate business plans in terms of feasibility, investment potential, risk, and completeness.
- Demonstrate the use of both verbal and non-verbal business communication.
- Effectively present business ideas and profile

091600611 Manufacture Parenteral

Overview: This Competency Standard covers the competencies required to apply skills and specific knowledge to perform manufacturing of parenteral products by involving collection of distal water, sterile raw materials, and sterilization of machine, equipment/tools and packaging materials in accordance with the industry's approved guidelines and procedures. The trainee will be expected to perform all competencies as per manufacturing order. The underpinning knowledge will be sufficient to provide the basis to start work.

Competency Units	Performance Criteria
CU1. Collect distal water	<p>P1. Start double distal water plant (Water for injection).</p> <p>P2. Drain water for few minutes as per specification.</p> <p>P3. Intimate section in-charge for further relevant process (e.g. pH, conductivity, sterility & pyrogen)</p> <p>P4. Receive report from section in-charge.</p>
CU2. Receive sterile raw materials	<p>P1. Receive sterile materials from pass through window as per specification</p> <p>P2. Transfer raw materials to concerned controlled area as per specifications (i.e. class A, B, C & D)</p> <p>P3. Report to in-charge about any deviation</p>
CU3. Perform sterilization of equipment & packing materials i.e. vials/ ampoules/bottles	<p>P1. Select sterilization methods.</p> <ul style="list-style-type: none"> • Filtration: use filtration for heat sensitive products. <ul style="list-style-type: none"> ○ Select appropriate filter size. • Terminal sterilization (autoclave) for heat resistant products. <ul style="list-style-type: none"> ○ Load product in autoclave. Lock its door properly. ○ Adjust pressure and temperature as per specifications. • Dry heat/chemical Sterilization <ul style="list-style-type: none"> ○ Sterilize vials/ampoules/bottles <p>P2. Collect product safely for further process.</p> <p>P3. Intimate section in-charge.</p>

<p>CU4. Mix materials</p>	<p>P1. Transfer specified volume of water for injection to different manufacturing tanks</p> <p>P2. Add and dissolve materials separately as per manufacturing order</p> <p>P3. Transfer solution as per specified method to storage tank through filtration</p> <p>P4. Report section in-charge about completion of process</p> <p>P5. Report any deviation to section in-charge</p>
<p>CU5. Control environment of production room</p>	<p>P1. Check environmental control parameters (Temperature, Humidity & particulate matters) through manufacturing order monometer/ hygrometer/ psychrometer / particle counter.</p> <p>P2. Receive area clearance report from section in-charge.</p> <p>P3. Report any deviation to section in-charge</p>
<p>CU6. Transfer product for filling and sealing</p>	<p>P1. Collect sample report form section in-charge</p> <p>P2. Transfer sterilized solution aseptically to filling area</p> <p>P3. Start filling and sealing under class "A" environment</p> <p>P4. Perform in process weight/volume variation & Optical checking</p> <p>P5. Shift filled product to quarantine area after terminal sterilization (where required) till approval from Quality Assurance</p> <p>P6. Report any deviation to section in-charge</p>

Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Describe specification of water.
- K2:** Define PH, conductivity, sterility & pyrogen
- K3:** Explain different types of distal water plants
- K4:** Elaborate operating procedure of distal water plant
- K5:** Describe types of controlled area
- K6:** Define sterile material

- K7:** Explain area classifications e.g. Class A, B, C & D
- K8:** Explain types of sterilization, types of filters
- K9:** Define autoclave
- K10:** Explain types of chemical sterilization and equipment.
- K11:** Define vials & ampoules
- K12:** Explain method of checking different types of environmental parameters
- K13:** Define monometer/ hygrometer/ psychrometer / particle counter.
- K14:** Define weight/ volume variation

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) to be competent in this competency standard:

- Demonstrate different sterilization process
- Perform weight/ volume adjustment
- Perform optical checking
- Read instrument digits

Tools and Equipment required

The tools and equipment required for this competency standard are given below:

- Double distilled water plant
- Containers
- Autoclave
- Dry Sterilizer
- Filtration Assembly
- Nominal filters
- Mixers
- Hygrometer
- Psychrometer
- Particle size counter
- Transfer pump
- Monometer
- Filling and sealing machine

091600612 Ensure Quality Product

Overview: This Competency Standard covers the competencies required to check quality raw materials in accordance with the Current Good Manufacturing Practices (CGMP) as well as industry's approved guidelines and procedures. Quality assurance and control play an essential role in the pharmaceutical manufacturing process, by ensuring that patients are provided with medications that are safe, effective, and produced at a high level of quality. Trainee will be expected to perform preventive measures for quality product as well as general housekeeping and maintenance of tools/equipment.

Competency Units	Performance Criteria
CU1. Ensure quality raw materials	<p>P1. Receive high quality raw materials as per the specifications of manufacturing order</p> <p>P2. Ensure materials identification labels as per the specifications of manufacturing order</p> <p>P3. Check expiry date on each labeled raw material as per specifications</p>
CU2. Check production equipment as per industry standards	<p>P1. Enlist equipment relevant to the task as per specifications given in manufacturing order</p> <p>P2. Identify tools/equipment relevant to the task as per Manufacturing order</p>
CU3. Give suggestions for process improvements	<p>P1. Identify problems on quality issues during completion of manufacturing order</p> <p>P2. Observe quality issues during manufacturing process</p> <p>P3. Identify objective measures for quality system effectiveness at manufacturing sites</p> <p>P4. Submit report to section in-charge</p>
CU4. Inspect production process	<p>P1. Ensure manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of industry</p> <p>P2. Reduce defect rate and waste of product by applying rules & regulations of industry for quality product</p> <p>P3. Ensure the availability of safe and effective drugs through Standard Operating Procedures of industry</p>

Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Define physical aspects of raw materials
- K2:** Describe requirements to check quality raw materials
- K3:** Explain quality standards
- K4:** Describe methods of ensuring quality for raw materials
- K5:** Define operation qualifications
- K6:** Define acceptance criteria
- K7:** Elaborate industry standards for production equipment
- K8:** Explain quality issues in manufacturing process
- K9:** Define techniques for solving issues in manufacturing process
- K10:** Elaborate how defect rates can be reduced in production

Critical Evidence (s) Required

The candidates need to produce following critical evidence(s) in order to be competent in this competency standard:

- Enumerate the steps that have been taken to ensure quality
- Summarize the implications
- Define pharmaceutical data
- Report writing

091600613 Complete Production Documentation

Overview: This Competency Standard identifies the competencies required to apply communication skills, knowledge and understanding to maintain documentations of all manufacturing raw materials and products in accordance with the industry's approved guidelines and procedure. Your underpinning knowledge is sufficient to provide you the basic knowledge for your work.

Competency Units	Performance Criteria
CU1. Maintain documentation of production	P1. Ensure documentation after completion of each batch P2. Maintain standard operating procedures and fill all the log books and other related Performa P3. Collect analysis reports and data sheet and handover to the person concerned after proper authentication, if required.
CU2. Prepare reports and data base	P1. Summarize information in proper format for decision making. P2. Select appropriate record source that is authentic and relevant. P3. Follow instructions of the management for preparing reports and database. P4. Submit report to the management timely to make decisions
CU3. Maintain all packaging record	P1. Perform manual inspections of packaging as per procedure P2. Assist physical inventory cycle counts accordingly P3. Communicate with upper management
CU4. Maintain record of equipment and batches	P1. Perform routine inspection as per procedure of industry P2. Ensure that each machine is in perfect shape before putting them to work P3. Maintain document after every repair or maintenance work P4. Keep record of maintenance work as per procedure

Knowledge and Understanding

The candidate must possess underpinning knowledge and understanding required to carry out tasks covered in this competency standard. Therefore, he/she must be able to:

- K1:** Read industry related policy matters
- K2:** Explain job related standard operating procedures
- K3:** Describe procedure of maintaining log books and another related Performa
- K4:** Explain procedure of maintain documentation
- K5:** Elaborate information on database
- K6:** Explain database on website
- K7:** Describe data sources
- K8:** Explain method of recording data and summarizing meaningful information for management.
- K9:** Describe process of record keeping
- K10:** Define importance of equipment
- K11:** Explain types of maintenance work

Critical Evidence(s) Required

The candidate needs to produce following critical evidence(s) in order to be competent in this competency standard:

- Record maintaining process
- Maintain raw materials receiving record
- How the equipment record check?
- Describe documentation used in the manufacturing of medicines

Tools/Equipment/Machines

Description

Liquid Manufacturing Tools and Machines

- Stainless steel tanks of different capacities
- Stainless steel spoons and scope
- Stainless steel transfer pipes
- PVC transfer pipes
- Filtration assembly
- Silver son mixer
- Homogenizer
- Slow mixer
- Transfer pumps
- Stainless steel buckets.
- Bottles blowing machine
- Bottles filling machine
- Bottles caps sealing machine
- Bottles labeling machine
- Autocartner packing machine
- Labels and unit carton printing machines

Solids Manufacturing Tools and Machines

- Stainless-steel high-speed mixing machine/ groove mixer
- Mixer machine for solution preparation
- Stainless steel wet granulation machine
- Fluidize bed dryer
- Tray dryer
- Stainless steel granulator
- Stainless steel blender
- Stainless steel buckets
- Stainless steel mesh of different sizes
- Compression machines
- Punches and dies
- Tablets De-dusting machine

- Coating assembly
- Tablets polisher
- Encapsulation machine
- Capsule polisher
- Dry suspension filling and sealing line
- Blistering/Strip machine
- Blistering machine molds, sealer and cutter
- Blister machine code punching digits and alphabets
- Blister packing Autocartner machine
- Unit carton printing machine

Parenteral Manufacturing Tools and Machines

- Stainless steel tanks
- Stainless steel spoons and scope.
- Stainless steel transfer pipes.
- Filtration clothes and cartages.
- Silver son mixer.
- Transfer pumps.
- Vials and ampoules washing and dryer machine.
- Autoclaves.
- Filling machines.
- Ampoules or vials sealing machine.
- Labeling machine.
- Blister machines.
- Blistering machine molds, sealer and cutter.
- Autocartner machine.
- Master carton sealing machine.
- Unit carton and ampoules or vials printing machine

