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**Gujarat Council of Vocational Training
Gandhinagar**



1. Name of Course: Pharmaceutical Machinery Mechanic

N.C.O. No. for Skills Covered:
(Please refer National Classification of
Occupations -2004 available
on www.dget.nic.in)

2. Engineering OR Non-engineering: **Engineering**

3. No. of students per batch: **20**

4. Duration in Hours. :Theory **342** hrs., Practical **349** hrs. Total **691** hrs.

5. Duration in Month: 6 @ **36** hours/Week.

6. Examination Scheme:

No.	Name of Subject	Teaching Hours during full course.	Maximum Marks. (Excluding Sessional)	Minimum Marks required for Passing (Excluding Sessional).	Sessional Marks if any.
Subject-1	Theory	342	100	40	100
Subject-2	Practical	349	300 ✓	120 80	100
Subject-3					
Subject-4					
Subject-5					

7. Entry qualification for Trainee:

Minimum entry qualification (Essential):	10 th + ITI(Fitter OR Electrician OR Instrument Mech OR RFM)
Desirable:	10th +2 year Experience of mechanical maintenance in Pharmaceutical Industry.

8. Minimum qualification for Trainer:

Minimum qualification (Essential):	DME
Desirable:	Exp. In Maint of Pharmaceutical machinery





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9. Syllabus Committee Member:

Sr. No.	Name	Organization	Designation	Technical Qualification	Exp in Years	Signature
1.	Mr.Col.V.K Sharma	Cadila Pharmaceuticals Ltd.	Chairman In IMC of ITI Vice President in Cadila	MBA	35	
2.	Mr. Brijen Patel.	Cadila Pharmaceuticals Ltd.	General Manager Engineering	B.E. Mechanical	22	
3.	Mr. Chetan Chauhan.	Cadila Pharmaceuticals Ltd.	Deputy Manager Engineering	B.E. Mechanical MBA Operation	09	
4	Shri D.P Makwana	RDD office Ahmedabad	Technical officer	Diploma in automobile Eng.	20	
5	Shri T.D Vyas	ITI Dhandhuka	Principal	B.E MECH	16	
6	Shri H.A Rathod	Dalwadi Industry, Dhandhuka	Vice Chairman	B.COM	25	

10. Terminal Skills of trainee: (Should be well defined and having reference to NCO):

The trainee, after successful completion of training, will have following skills...

1. Please See the separate sheet.

2.

3.

4.

5.





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Skills

- (1). Understanding of problems of pharmaceutical mfg. operations.
- (2). Troubleshooting.
- (3). Awareness towards needs of pharmaceutical mfg. practices.
- (4). Overall mfg. process know how
- (5). Technical know - how far pharmaceutical mfg. technology.
- (6). Thermal, Electrical and Atomization techniques.
- (7). Energy conservative minds of knowledge of application.
- (8). Awareness for hygiene & safety of man, machine and materials.
- (9). GMP complied engineering knowledge.
- (10). Core competence of pharmaceutical engineering system.





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11. Approximate cost of Tools / Equipments / Machinery for Starting one batch of the course:

Rupees
50 Lac.

Reference Year
August 2013

12. Area required for practical / Workshop for on batch.

.....**120**..... Sq. Meter

13. Minimum Power connection required

.....**18.32**..... K.W.

14.1 No of items in Standard list of Machinery:

14.1.1. Page NO from ___ to ___.

Please see attachment

14.2 No of items in Standard list of Shop outfit :

14.2.1. Page NO from ___ to ___.

Please see attachment

14.3 No of items in Standard list of Trainee Toll-Kit :

14.1.1. Page NO from ___ to ___.

Please see attachment

***** FOR OFFICIAL USE *****

Approved by GCVT ~~in Governing Body meeting~~ on

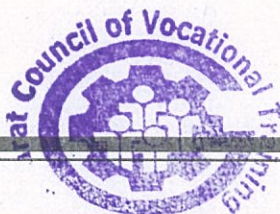
: **16/03/2013**

Syllabus implemented w.e.f. admission session

: **Next session.**

Revision History :

1. Revision No..... Revision Date.
2. Revision No..... Revision Date.
3. Revision No..... Revision Date.





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કૌશલમ્ વલમ્

Standard List of Machinery - Equipment / Shop-outfit / or Trainee Toolkit
for Trade of **Pharmaceutical Machinery Mechanic**

Sr. No.	Description of Item with detailed specifications	Item type i.e. Machinery / Equipment OR Shop Outfit OR Trainee Toolkit	Quantity Required per one Batch of Students	Quantity Required per one Batch of Students for Instructor	Total Quantity Required (Total of previous two columns)
1.	Tablet & HGC Capsule Machinery				
	(A) Dispensing				
	➤ Laminar Air Flow & Reverse Laminar Air Flow	Shop outfit	1	0	1
	➤ Solvent Transfer Pump	Machinery	1	0	1
	➤ Vibro Sifter	Equipment	1	0	1
	(B) Granulation				
	➤ RMG	Equipment	1	0	1
	➤ FBD	Equipment	1	0	1
	➤ Tipler	Equipment	1	0	1
	➤ Tilting & Lifting Device	Shop outfit	1	0	1
	➤ Communiting Mill	Equipment	1	0	1
	➤ Multimill	Equipment	1	0	1
	➤ Mixer	Equipment	1	0	1
	➤ Sifter	Equipment	1	0	1
	➤ Blender	Equipment	1	0	1





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(C)	Tablet Compression				
	➤ Tablet Compression	Equipment	1	0	1
	➤ De duster	Equipment	1	0	1
	➤ Air Displacement Unit	Equipment	1	0	1
(D)	Capsule Filling				
	➤ Capsule Filling & Sealing	Equipment	1	0	1
	➤ Accessories	Shop outfit	1	0	1
(E)	Coating				
	➤ Auto coater	Machinery	1	0	1
	➤ Colloid Mill	Machinery	1	0	1
	➤ Homogenizer	Equipment	1	0	1
(F)	Inspection				
	➤ Automatic Inspection Machine	Machinery	1	0	1
(G)	Primary Packing				
	➤ Strip Pack	Machinery	1	0	1
	➤ Blister Pack	Machinery	1	0	1
	➤ Defoiling m/c	Machinery	1	0	1
	➤ Bulk Packing line	Machinery	1	0	1
(H)	Secondary Packing				
	➤ Cartnetor	Equipment	1	0	1
	➤ Inspection M/Cs	Machinery	1	0	1
	➤ BOPP sealing m/c	Machinery	1	0	1
	➤ Litrecher folding M/c	Machinery	1	0	1
	➤ Conveyor Belt	Machinery	1	0	1



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2.	Oral Liquid Machinery				
	➤ Manufacturing Vessels	Equipment	1	0	1
	➤ Liquid Transfer Pumps	Machinery	1	0	1
	➤ Bottle Washing M/C	Machinery	1	0	1
	➤ Bottle Filling M/C	Machinery	1	0	1
	➤ Bottle Sealing	Machinery	1	0	1
	➤ Measure Cup Placing & Pressing	Equipment	1	0	1
	➤ Labeling m/c Packing Machinery	Machinery	1	0	1
3.	Injection Manufacturing Machinery				
	➤ Autoclave	Machinery	1	0	1
	➤ Elastomer Closer Treatment	Machinery	1	0	1
	➤ Dry Heat Sterilizer.	Machinery	1	0	1
	➤ Manufacturing Vessels	Machinery	1	0	1
	➤ Liquid Transfer Pumps	Machinery	1	0	1
	➤ Washing M/C	Machinery	1	0	1
	➤ Filling M/C	Machinery	1	0	1
	➤ Sealing M/C	Machinery	1	0	1
	➤ Inspection M/Cs	Machinery	1	0	1
	➤ Labeling m/c	Machinery	1	0	1
	➤ Packing Machinery	Machinery	1	0	1
	➤ Lypholizer	Machinery	1	0	1





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4.	Utility Machinery				
	➤ Boiler	Machinery	1	0	1
	➤ Chiller	Machinery	1	0	1
	➤ Air compressor	Machinery	1	0	1
	➤ Nitrogen plant	Machinery	1	0	1
	➤ Cooling tower	Machinery	1	0	1
	➤ D G set	Machinery	1	0	1
	➤ RO Plant	Machinery	1	0	1
	➤ Pure steam generator	Machinery	1	0	1
	➤ Multi column distillation plant	Machinery	1	0	1
	➤ Air Handling Units	Machinery	1	0	1
5.	Shop outfit				
	➤ Steel Rule 30 cm to read Metric	Shop outfit	4	0	4
	➤ Drill twist s/s 1.5 to 12mm by 0.5 mm	Shop outfit	1set	0	1set
	➤ File Triangular 15cm smooth	Shop outfit	2	0	2
	➤ File round 20 cm second cut	Shop outfit	2	0	2
	➤ File square 15 cm second cut	Shop outfit	2	0	2
	➤ Pliers combination 15 cm	Shop outfit	2	0	2
	➤ C Clamp 5 cm	Shop outfit	1	0	1
	➤ Chisel cold 19 mm flat	Shop outfit	4	0	4
	➤ Vernier caliper 20cm	Shop outfit	1	0	1
	➤ Pipe wrench 30cm	Shop outfit	1	0	1
	➤ Bench vice 125mm	Shop outfit	8	0	8

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6.	Trainee Tool Kit				
	➤ File flat 25 cm second cut	Tool kit	20	1	21
	➤ File flat 25 cm bastard	Tool kit	20	1	21
	➤ File half round 15 cm second cut	Tool kit	20	1	21
	➤ Square try 10 cm Blade.	Tool kit	20	1	21
	➤ Caliper outside 15cm spring	Tool kit	10	1	11
	➤ Caliper inside 15 cm spring	Tool kit	10	1	11
	➤ Punch center 10 cm	Tool kit	20	1	21
	➤ Straight Scriber 15 cm	Tool kit	10	1	11
	➤ Hammer ball peen 0.45 kg with handle	Tool kit	10	1	11
	➤ Hacksaw frame fixed 30 cm.	Tool kit	10	1	11
	➤ Dot slot punch 10cm	Tool kit	10	1	11

(As many sheets as required should be used to accommodate all items)





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Sr. No.	Theory	Duration		
		in Hrs.		
1	Introduction to Pharmaceutical Sector	10		
	Definition and Scope,			
	Introduction of different segments of Pharma Insudtry			
	Classification of Dosage forms with their examples and application.			
2	Basic Understanding on GMP:	20		
	Definition and scope,			
	Basic Requirements of GMP in Pharma Industry,			
	Principal of GMP,			
	Commandments of GMP,			
	Current terminology,			
	Schedule M & WHO			
3	General Introduction:	10		
	Objective and Scope to Pharmaceutical machinery mechanic / operator			
	Awareness about pharmaceutical sector			
	Introduction to regulatory and statutory guide line for pharmaceutical Industry.			
	General Introduction to pharmaceutical operations including function of different department and brief overview of operations			
	Induction & Orientation Program			
	Company Overview			
	Familiarization of Plant Activities,			
	Types of Work and Responsibility			
	4		Introduction of different Pharmacopoeias	2
			Significance in Pharma industry with special reference to the Indian Pharmacopoeia	
5	Health, Safety and Environment:	5		
	HSE Policy			
	Safety Awareness Program			
	Overview of Safety in Pharmaceutical industry.			
	Industrial visit	8		





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Part - II		
6	Introduction to Core Operations of Pharma Industry	10
	Basic Process Segments of Pharma Industry	
	Overview of Solid Oral Process	
	Overview of Liquid Oral Process	
	Overview of Injectables Process	
7	Solid Oral	40
	Tablet, Capsule & Semi Solid	
	Process Flow diagram of Tablet	
	Definition and Scope	
	Different type of Tablets and their application	
	Different type of Manufacturing Process	
	Definition of Active Ingredient and Excipients	
	Defects in Tablets	
	Physical parameters involved in Tablets	
	In-process checks	
	Operation, Cleaning and Maintenance of	
	Compression machine, De-dusting machine and	
	Metal detector,	
	Types of Tablet tooling	
	Dispensing of Raw Material	
	Definition & Scope	
	Size Separation (Sifting):	
	Definition and scope	
	Official Standards for powders	
	Operation, Cleaning and Maintenance of	
	Mechanical sifter, Vibro sifter etc.	
8	Size Reduction (Milling):	10
	Definition and Scope	
	Methods of size reduction	
	Factors affecting size reduction,	
	Operation, Cleaning and Maintenance of	
	Communing mill, Cad mill Multi mill etc.	
9	Mixing and Homogenization (Mixing & Granulation):	10
	Definition and Scope	
	Types of Mixing, Examples of Mixer	
	Homogenizer Operation, Cleaning and	
	Maintenance of RMG, PLM, Blender etc	





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10	Drying: Definition and scope Types of Dryers Operation, Cleaning and Maintenance of Tray dryer, FBD FBE, FBP, Spray drying etc.	10
11	Tablet Coating: Definition and Scope Advantage of Coating Types of Coating Types of Coating machine Operation, Cleaning and Maintenance of Coating machine, Defects in Coated Tablets Tablet inspection In-process checks	10
12	Capsules: Definition and scope Hard and Soft gelatin capsules Capsules of different sizes Advantages of Capsules, Operation, Cleaning and Maintenance of Capsule filling machine, Filling of capsule Storage & handling of capsules. In-process checks	20
13	Liquid Orals: Definition and scope Type of liquid orals, Monophasic liquid and Biphasic liquid dosage forms Types of Monophasic liquids for internal and external administration, Mixing process Filtration: Definition, Theory of Filtration, Filter media Selection of filter and filter aids, Operation, Cleaning and Maintenance of Filtration Equipments life Filter Press. Theoretical aspects of vehicles, and essential adjuvant like stabilizers, colorants, flavors with examples, Biphasic Liquid dosage forms- Suspension,	30





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	Preparation of suspension, Study of adjuvants like thickening agents, wetting agents, etc and their necessity and quantity to be incorporated, Introduction to flocculated and non-flocculated suspension system. Manufacturing of liquid orals, Physical parameters involved in liquid orals and their significance, Biphasic Liquid dosage forms-Emulsion Definition and type of Emulsions, Formulation of emulsions In-process checks Operation, Cleaning and Maintenance of Liquid filling line, Cleaning of utensils used in manufacturing	
14	<p>Injectables</p> <p>Definition and scope</p> <p>Introduction of Injectable Manufacturing Facility</p> <p>Introduction of Aseptic Area</p> <p>Entry & Exit & Gowning procedure for Sterile Area</p> <p>Flow diagram of Injectable Manufacturing Process</p> <p>Ampule / Vial Washing & Sterilization</p> <p>Operations & Maintenance of Ampule / Vial Washing Machine</p> <p>Ampule / Vial Filling & Sealing Process</p> <p>Operations & Maintenance of Ampule / Vial Filling Machine</p> <p>Terminal Sterilization</p> <p>Operations & Maintenance of Autoclave</p> <p>Operations & Maintenance of Laminar Air Flow Unit</p> <p>Operations & Maintenance of Isolator</p> <p>Inspections</p> <p>Operations & Maintenance of Ampule / Vial Washing Machine</p> <p>Ampule/Vial Washing & Sterilization</p> <p>Operations & Maintenance of Ampule Washing Machine</p> <p>Ampule/Vial Washing & Sterilization</p> <p>Operations & Maintenance of Ampule Washing Machine</p>	30





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15	Packing of Pharmaceutical products:	20
	Definition & scope	
	Types of Packing materials	
	Advantages of Packing	
	Merits and demerits of different packing materials	
	Description of printed text matter	
	Operation, Cleaning and Maintenance of	
	Machines related to packing line,	
	Operation of Leak test apparatus,	
	In-process checks	
	Industrial visit	8
	Part - II (B) : Pharma Utilities	
16	Introduction to Utility of Pharma Industry	10
	Power Generation & Distribution Systems	
	Over view of electrical distribution system	
	DG Set	
	Transformer	
	PCC, MCC & DB Panels	
17	Introduction to Utility of Pharma Industry	50
	Power Generation & Distribution Systems	
	Over view of electrical distribution system	
	DG Set	
	Transformer	
	PCC, MCC & DB Panels	
	Steam generation & distribution system	
	Boiler	
	Fuel Storage & Handling system	
	Flue Gas Exhaust System	
	Steam Piping & Distribution overview	
	Overview of IBR Guidelines	
	Water Treatment Plant	
	Raw Water - Bore Well & Storage Tanks	
	Chlorination Process	
	Pre treatment for Purified Water	
	Soft Water System	
	RO Water System	
	Purified Water System	
	Water For Injections System	
Pure Steam Generators		
Refrigeration & Air Conditioning System		





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	Chiller	
	HVAC System	
	Clean Room	
	Domestic Refrigeration & Air Conditioning System	
	Sub Zero Refrigeration	
	Compressed Air & Nitrogen Gas System	
	Air Compressor	
	Air Dryer	
	Nitrogen Generation System	
	Air & Nitrogen distribution & application overview	
18	Part - II -C Introduction to Automation In Pharma	25
	Basic Instrumentation	
	Introduction to PLC, HMI, MMI and other Instrument.	
	Introduction to Energy Conservation through Automization (VFD, VSPS Systems etc)	
	Importance of calibration, scope of calibration section, standard procedures of calibration of different instruments.	
19	Part - II -D Introduction to Calibration, Qualification & Validation Process	10
	Importance of calibration, scope of calibration section, standard procedures of calibration of different instruments.	
	Over view of Equipment Qualification & Process Validation systems	
20	Part - II -E Documents & Data Recording System	10
	Type of documents to be maintained in pharma	
	Over of SOPs, Change control & other documentation process	
	Industrial visit	8

Sr. No.	Practical	Duration Hrs.
1	Round in the Plant, Familiarization with different plants, service departments and their function	10
2	-----	
3	Exposure to Practical Training	5
4	Introduction with different manufacturing system, types of products manufactured in plant	20





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5	-----	
6	-----	
7	Operation, Cleaning and Maintenance of Weighing balances and measuring devices	10
8	Understanding on basic principal of different types of Equipment/ Machine used in processing of Pharma products, Operation of PLC Preparation of following formulations: Solutions Suspension Emulsion Powders Tablets Capsules etc.	50
9	Understanding on different types of Compression Machine, Identification and Setting of accessories, Identification of Tooling, Operation, Cleaning and Maintenance of Compression machine, De-duster and Metal detector, Checking of in-process parameters involved in tablets compression	50
10	Operation, Cleaning and Maintenance of Capsule filling machine, Identification and setting of accessories Checking of in-process parameters involved in capsule filling	
11	Operation, Cleaning and Maintenance of Liquid filling machine, Bottle washing machine, Identification and setting of change parts, Measurements of pH, Volume of the solution Checking of in-process parameters involved in liquid orals	50
12	Operation, Cleaning and Maintenance of all machines involved in Packing of pharmaceuticals	50
13	Study of Human skeleton Study with the help of charts and models of following system- Respiratory system Digestive system Cardiovascular system	20



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	Central nervous system Urinary system Reproductive system Sense organs (Eye, Ear, etc.) Recording of BP, Pulse, Heart rate and ECG	5
14	Practical understanding on water system Generation and Distribution of Purified Water	20
15	HVAC system and other utilities support in the plant	20
16	Cleaning procedure	20
	EXAM	

