Marwadi University

Date: 14-10-2021

Office Order

Subject: Office order to depute Dr. Vicky Jain,at Almelo Private Limited to receive training as a part of Faculty Industry Immersion programme (FIIP).

Dr. Vicky Jain, Associate Professor, Department of Chemistry, Faculty of Science, Marwadi University is deputed at Almelo Private Limited, Unit-II, Hydrabad, Telangana from 19th October, 2021 to 23rd October, 2021 to receive training as a part of Faculty Industry Immersion Programme (FIIP) to acquire industry knowledge on various attributes of research and development, manufacturing, raw material warehouse and quality control. In connection with this he is entitled for on duty leave during the mentioned period.

Dean-Research
Prof. (Dr.) R.B Jadeja
Marwadi University
Rajkot

Copy to:

1. Deans and Principals of University
2. Head - HR
3. Concern File

MARWADI UNIVERSITY * RAJKOT *

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+91 89800 30090 | +91 281 7123456

October 23, 2021

CERTIFICATE

This is to certify that **Dr. Vicky Jain**, Associate Professor from Marwadi University, Rajkot-360003, Gujrat India has undergone training at Almelo Private Limited, Hyderabad from 19th October, 2021 to 23rd October, 2021 as a part of Faculty Industry Immersion Programme (FIIP). He has successfully completed his training and has acquired industry knowledge on various attributes of the Research and Development, Manufacturing, Raw Material warehouse, and Quality Control department at **Almelo Private Limited, Unit-II**, Survey Nos. 227, 228 & 137, 136, Shabashpally (V), Shivampet (M), Medak District-502 334, Telangana.

Thanking You,

For Almelo Private Limited,

ALMELO PRIVATE LIMITED ★ HYDERABAD ★

Dr Keshav Deo
Executive Director

Marwadi University

FoS
Faculty of Science

FIIP REPORT

19th October, 2021 to 23rd October, 2021

- Dr. Sabera Bijani & Dr. Vicky Jain

Department of Chemistry

A short description of the site:

The manufacturing site is located in Shabashpally village, which is approximately 56 kilometers from Hyderabad city. The site is planned to have adequate plant landscaping across the site. Distance of this site from nearby international airport (Rajeev Gandhi international Airport) is about 90 kilometers and approximately 70 kilometers from major railway station (Secunderabad Railway Station); the availability of these facilities provide ease in transporting materials to the site and also from the site. This indicates that this site is good in terms of connectivity and ease in material movement.

The plant is surrounded by fields on either side hence ensuring no disagreeable, obnoxious odor's, soot, dust or smoke hamper the quality of products produced at Almelo Pvt. Ltd. This site, Unit-II is the second site of Almelo Pvt. Ltd in India and is involved in the manufacturing activities of API & Intermediate.

Quality management systems (QMS) :

- Quality Management system is established, documented and maintained in accordance with the requirements of cGMP guideline ICH Q7 and schedule M.
- Quality Management systems like Change control system, Deviation handling, internal audits, and quality risk management are in place to ensure compliance with quality standards of cGMP ICH Q7.

Batch certification and releasing procedure:

- Quality Assurance department is authorized for release the material to market. The authorized persons are trained on the respective QA release activity before the execution (SOP No. QA/033, Title: Batch release).
- QA representative initiates the batch release upon the receipt of the OPD (Order Processing Document / STO (Stock Transfer Order) (SOP No. QA/033, Title: Batch release).
- QA representative ensure the completion of the batch records and related documents of dispatch including all input intermediate batch records. (SOP No. QA/009, Title: Preparation, issue, filling and verification of BPR)
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- QA representative generates QA release label and a specimen copy of all approved labels are attached in BPR (SOP No. QA/047, Title: Guidance for Preparation of Labels).

- Ensures that the manufacturing date and Expiry/Retest date assigned on product label is according to stability data. (SOP No. QC/072, Title: Stability study)
- On competition of verification and pasting of QA release labels to the containers, QA representative releases the batch intended for sale. (SOP No. QA/033, Title: Batch release).
- All the original dispatch documents are retained by QA. The retained records of distribution gives full batch traceability from factory to the customer/ regulatory agencies, in terms of date of sale, customer details and quantity dispatched. (SOP No. QA/003, Title: Document control (Archival, retention & Disposal of documents).

Personnel hygiene requirements, including clothing: (SOP No. QA/050, Title: Personal Hygiene)

- Personnel working in manufacturing and other cGMP areas are trained on personnel hygiene standards. Personnel working in manufacturing and other cGMP area follow the established entry-exit procedure. Personnel use a well-defined gowning procedure to ensure maintenance of hygiene and prevention of cross contamination. This change philosophy is based on the unit operations involved. Strict adherence to dress code is maintained in clean rooms where finished product is handled. All visitors are provided with necessary clothing when they visit various areas of manufacturing. Facilities are provided for employees to wash their hands whenever required with disinfectants. Personnel are not allowed to eat, drink, and chew gum or tobacco inside the manufacturing facility. All the personnel wear safety equipment like helmet, safety goggles.etc when they enter the manufacturing area. Pest control SOP is in place to control insects, rodents; etc. in specific area. And general wash facilities are provided at work areas and in canteen.
- Number of employees engaged in the quality management, manufacturing, quality control, storage and distribution respectively:

Department	No. of employees
Manufacturing	23
Quality Control	10
Quality Assurance	15
Warehouse	06
Engineering	25
Human Resource Development	03
Safety, Health & Environment	04
Information communication and technology	01
Total	97

Premises:

The manufacturing block consists of change areas, manufacturing area and technical area. QA, QC and administration departments are housed in Almelo house independently; Remaining departments such as OHC, Utility etc. are housed independently.

The typical unit operation to be undertaken in the facility are as follows:

- Crystallization
- Filtration
- Drying
- Sifting and blending operations.

Brief description of water systems

The source water for the water treatment plant is Bore well water. Water from the bore wells is drawn out through submersible pumps and stored in a RCC Tank. The flooring, walls and slab of the RCC tank is epoxy coated. Water is distributed from the tank through pumps, which are input to the water system.

Water from the RCC tank is dosed with NaOCl to inhibit microbial growth. This water then passes through 50 µ cartridge filters and UF system to control SDI & TSS. The permeate from the UF modules is stored in 2000 liters storage tank. This water is then transferred to CSRO modules.

Before feed to RO modules the water is dosed with anti-scalent, acid and SMBS dosing to maintain the required quality aspects of water in terms of pH, chlorine free. The water after Ultrafiltration & reverse osmosis is stored in the 5000 liters intermediate water storage tank. The water in the intermediate storage tank is dosed with ozone for microbial control. The ozonized water then passes through UV where destruction of residual ozone happens. The water is then transferred to HSRO modules through a multi purpose storage tank. The RO permeate water is then passed through electro-deionization (HSEDI) unit. Continuous EDI removes ions from water using ultra-pure ion exchange resin. The post UF polishes the RO – EDI permeate further to enhance the permeate water quality by limiting the microbial count. Post - Ultra filtration unit is equipped to specifically reduce the endotoxins. Endotoxin reductive limit is 0.25 EU/ml. Will be allowed to pass through RO, EDI & UF to get purified water. Purified Water generated in the generation system is stored in vertical tank of operating capacity 10000 Liters. This purified water is then distributed to various point of use and referred after passing through UV. The water is circulated to plant through loops and system is sanitized with hot water as per schedules

Inbuilt Water system facility at Almelo Pharmaceuticals

Equipment:

Listing of major manufacturing and Quality control laboratory equipment's:

The major manufacturing equipment's include Glass lined reactors (GLR), SS reactors, receivers, centrifuges, filters, Rotary vacuum paddle drier (RVPD), Millers, Sifters are used to carry out the various types reactions, filtrations, drying and physical operations.

The QC laboratory has adequate chemicals and glassware for routine analysis. Also equipped with sophisticated instruments such as HPLC, GC, FTIR, Polarimeter, UV spectrophotomer, TOC analyzer, Karl fisher, IR moisture balance, analytical balance, pH meter etc are provided for analysis. Microbiology laboratory is equipped with incubator, autoclave, LAF etc.

EQUIPMENTS	**Equipment Type**	**Number of Equipment**	**CAPACITY**
Reactors SS & GLR	SSR	3	5 KL
	SSR	1	1 KL
	SSR	6	10 KL
	SSR	3	12 KL
	SSR	1	6 KL
	SSR	4	0.6 KL
	SSR	3	300L
	SSR	1	250L
	SSR	2	50L
	SSR	2	3 KL
	SSR	1	100L
	GLR	2	5 KL
	GLR	4	630L
	GLR	1	100L
ANFD	ANFD	3	7KL
	ANFD	1	10KL
	ANFD	1	0.5 KL
	ANFD	1	0.15 KL
RVPD	SF-RVPD	1	3 KL

RCVD	GF-RCVD	1	100 Kgs
	GF-RCVD	1	2 KL
VTD	GF-VTD	1	6 Trays
	SF-VTD	1	24 Trays
	SF-BDCF	1	746L
	TF-BDCF	1	746L
Centrifuge	GF-BDCF	1	746L
	FF-TDCF	3	24”
	FF-PM	1	100 kg/hr
Pin mill	FF-PM	1	15 kg/hr
	GF-MM	1	25 kg/hr
	GF-MM	1	250 kg/hr
Leaf filter	SF-LF	2	50 L
	GF-SF	2	36 inch/30 inch
Sparkler Filter	GF-SP	1	200 L
	FF-PNF	1	30L
Pressure Nutsche filter	FF-PNF	1	500L
	FF-PNF	1	450L
	SF-PNF	1	30L
Blenders	GF-BL	1	1600L
Hot air oven	GF-HAO	1	125 L
Nitrogen selear	GF-NIS	1	3 Kg
	GF-BC	2	60TR
	GF-BC	1	150TR
	GF-BC	1	26 TR
Air Compressors	GF-CA	1	136 CFM
	GF-CA	1	114 CFM
Air Dryers	GF-AD	1	100 CFM
Nitrogen Plant	GF-NS	1	50 nm^3/Hr

	FDV (Forced draft ventilation)	4	16000 CFM
Air Handling Units	AHU	1	10525 CFM
	AHU	1	4508 CFM
	AHU	1	7252 CFM
	AHU	1	8699 CFM
	AHU	1	9227 CFM
	AHU	1	5675 CFM
	AHU/QC	1	2581 CFM
	AHU/QC	1	2797 CFM
	AHU/RW	2	4500 CFM
	AHU/RW	2	4000 CFM
	AHU/RW	5	1000 CFM
	AHU/RW	1	8000 CFM
Purified Water System	PWS	1	21000 Ltrs/Hr
	SS 316L Storage Tank	1	5 KL
	RO1(Reverse Osmosis)	1	2.6 CuMtr/Hr
	RO2(Reverse Osmosis)	1	2.2 CuMtr/Hr
Purified Water	Post UF system	1	2.0 CuMtr/Hr
	ED1(electro-deionization)	1	2.1 CuMtr/Hr
	SS 316L Purified storage tank	1	10 KL
	Ozoniser	1	25 g/hr
MEE	GF-MEE	1	2000 Kg/hr
Boiler	GF-BO	2	4.5 Tons
	GF-BO	1	2.8 Tons
	FF-HWS	3	100 CuMtr/Hr
Hot Water Generator	FF-HWS	1	20 CuMtr/Hr
	GF-CT	3	250 TR

	GF-CT	2	150 TR
Cooling Tower	GF-CT	1	60 TR
Liquid Nitrogen tank	UT-GF-LNS-01	1	13 KL

INSTRUMENT NAME	**MAKE**	**MODEL**
ANALYTICAL BALANCE	METTLER TOLEDO	XPE205D R
MICRO BALANCE	METTLER TOLEDO	XPE26
PRECISION BALANCE	METTLER TOLEDO	XPE1203S
ANALYTICAL BALANCE	SCALE TECH	SAB224CL
PH METER		S400
PH METER/ CONDUCTIVITY METER	METTLER TOLEDO	S400 Bio
GC	AGILENT	7890B
HPLC	AGILENT	1260 Infinity
FT-IR	PERKIN ELMER	SPECTRU M TWO
UV SPECTRO PHOTOMETER	AGILENT	CARY 60
POLARIMETER	ANTON PAAR	MCP 200
LAMINAR AIR FLOW	ICLEAN	N/A
Biosafety Cabinet	ICLEAN	NA
Dynamic passbox	Iclean	NA
STABILITY CHAMBER	NEWTRONIC	NLHC16SI
COOLING CHAMBER	NEWTRONIC	NLCC16SI
PHOTOSTABILITY CHAMBER	NEWTRONIC	NLPS16SI
BOD INCUBATOR CHAMBERS	NEWTRONIC	NLBOD16 SI
HOT AIR OVEN	Meta Lab	NA
AUTO TITRATOR	METTLER TOLEDO	T5

KF TITRATOR	METTLER	T7
GAS FLOW METER	AGILENT	ADM1000
DEEP FREEZER	Haier	DW- 40L262
HOT PLATE	Meta Lab	GMP model
VACUUM OVEN	Meta Lab	GMP
REFRIGETATOR	SAMSUNG	DIGITAL INVERTER
CYCLOMIXER	REMI	CM101
MUFFLE FURNACE	Meta Lab	GMP
WATER BATH	Meta Lab	GMP
VACUUM PUMP	Rocker	NA
PETRI SAMPLING SYSTEM	HIMEDIA	LA367
STERILISATION AUTOCLAVE	PHARMALAB	NA
DECONTAMINATION AUTOCLAVE	MACHIN FABRIK	
HALOGEN MOSITURE ANALYSER	METTLER TOLEDO	HX204
MILLIQ WATER SYSTEM	MERCK MILLIPORE	Elix
Microscope	Olympus	CH20i
Digital colony counter	ESICO	361
Fogger	Spurthi	NA
Dry bath	Rocker	310 Sahara
Hot air oven	Willington Electrolab (india) private limited	NA
Electromagnetic sieve shaker		EMS-8

Manufacturing block

GMP critical computerized systems

The manufacturing and analysis aspects involves the usage of computerized systems. All the computerized systems that are used for manufacturing and analysis shall be tested and calibrated as per the regulatory requirements and GMP compliance. Audit trials, periodical performance/ calibration checks and will be conducted for the respective computerised systems to ensure the adequacy for the operations being used.

DOCUMENTATION:

As part of cGMP requirements, the company is involved in the documentation activity, which provides a means for the company to retain all the records of its activities. The documentation system i.e. initiation, approval and distribution of documents carried out as per defined procedure. Standard formats and instructions are available for preparation of all major documents. The available documents are Specifications and Method of analysis of Raw Materials, Packing Materials, Intermediates and Finished drug substances, Standard Operating Procedures of all departments, Batch Production Records, Packing Record, Analytical Record etc. The documents are retained as per their respective retention period.





Some Photographs of Raw Warehouse Department








Some Photos of Manufacturing block

Handling of rejected materials and products: (SOP No. WH/012, Title: Handling of Rejected Materials)

Any material that is rejected and found not conforming to the requirements or specifications is treated as "Rejected Materials". In such cases, QC affixes 'Rejected 'labels on each such container and rejection note is prepared giving reasons for Rejection. The stocks are moved to an area designated for rejected stocks and kept under lock and key. The rejected material is reprocessed / reworked / disposed as per procedure and documented. Containers are sealed with tamper evident having unique number and the seals details were captured in the packing record for reference.

The SCM informs the vendor of rejection along with reason for rejection. The rejected material then sent back to the vendor or disposed.

QUALITY CONTROL (QC):

The Quality Control facility is well equipped with sophisticated instruments. The objective of Quality Control is to collect analyze various materials such as raw materials, in process, intermediates and Finished Drug Substances as per the existing standard test procedures. QC is authorised to approve / reject the material based on the test results and is independent from manufacturing. Some of the prime activities are as follows.

- All chemical, physical and microbial analysis shall be carried out as per Specification & Method of analysis. Approve or reject raw materials, Packing components, In-process materials, intermediate material and finished drug substances based on the testing and analytical acceptance criteria and predetermined specification.
- Preparation or revision of specification, Analytical Methods and procedures, which directly or indirectly contribute to the identity, strength, quality and purity of the company's products.
- Investigation of non-conforming material.
- Investigate complaints relating to the analytical quality of the company's products.
- Review and retain all records relating to the testing and approval of raw materials, packaging components, in-process materials, intermediate and Finished Drug Substance.
- Approve or Reject the proposed new sources of supply of raw materials and packaging components

- Maintain a stability program, enter results in stability program formats, and make retest date/expiry date recommendations based on the results. Participate in the development, implementation, and maintenance of cGMP & GLP.
- Finished Drug Substance release.
- Method validations, analytical validations and key raw material method validation.
- Calibration of instruments in Quality Control.

Microbiological testing shall be performed in the site for the finished products, facilities and water etc. as per the requirement

Well equipped QA department at Almelo Pharmaceuticals

SELF INSPECTIONS: (SOP No. QA/008, Title: Internal Audits)

Self-Inspections are carried out with the objective of ensuring the implementation and compliance of cGMP. Inspection team from cross-functional department's audit the identified departments as per the schedule for compliance of laid down systems and procedures. Such inspections are carried out as per a defined procedure and frequency.

Self-Inspections is conducted every three months in a year to check the compliance and to lay down procedures / guidelines of Quality Management System and Good Manufacturing Practices. Non-compliance report is given to auditee for which corrective and preventive actions are to be taken. Internal audits shall be performed as per schedule approved by QA. The personnel conducting the audit are trained either externally or internally. Internal audits are undertaken by

qualified personnel who are not directly responsible for the area being audited. Other than QA personnel, individuals from cross-functional areas are selected and trained as internal quality auditors to perform internal auditing. Upon completion of the audit, the audit findings are reviewed with all the respective department heads. The audited departments individually respond to the findings in the audit report and detail about the correction, corrective and preventive actions taken. The corrective and preventive actions are verified in the follow up audit. Effectiveness of the self inspection program and status of completion of actions shall be reviewed timely under management review system.

Acknowledgement

I, Dr. Vicky Jain and Dr. Sabera Bijani are very thankful to the Marwadi University for allowing us to visit Almelo Pharmaceuticals under FIIP programme.

Marwadi University

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almelo

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Dr Keshav Deo
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ALMELO PRIVATE LIMITED, UNIT-II
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CIN No : U24110TG1979PTC002536
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	TF-BDCF	1	746L
Centrifuge	GF-BDCF	1	746L
	FF-TDCF	3	24”
	FF-PM	1	100 kg/hr
Pin mill	FF-PM	1	15 kg/hr
	GF-MM	1	25 kg/hr
	GF-MM	1	250 kg/hr
Leaf filter	SF-LF	2	50 L
	GF-SF	2	36 inch/30 inch
Sparkler Filter	GF-SP	1	200 L
	FF-PNF	1	30L
Pressure Nutsche filter	FF-PNF	1	500L
	FF-PNF	1	450L
	SF-PNF	1	30L
Blenders	GF-BL	1	1600L
Hot air oven	GF-HAO	1	125 L
Nitrogen selear	GF-NIS	1	3 Kg
	GF-BC	2	60TR
	GF-BC	1	150TR
	GF-BC	1	26 TR
Air Compressors	GF-CA	1	136 CFM
	GF-CA	1	114 CFM
Air Dryers	GF-AD	1	100 CFM
Nitrogen Plant	GF-NS	1	50 nm^3/Hr

	FDV (Forced draft ventilation)	4	16000 CFM
Air Handling Units	AHU	1	10525 CFM
	AHU	1	4508 CFM
	AHU	1	7252 CFM
	AHU	1	8699 CFM
	AHU	1	9227 CFM
	AHU	1	5675 CFM
	AHU/QC	1	2581 CFM
	AHU/QC	1	2797 CFM
	AHU/RW	2	4500 CFM
	AHU/RW	2	4000 CFM
	AHU/RW	5	1000 CFM
	AHU/RW	1	8000 CFM
Purified Water System	PWS	1	21000 Ltrs/Hr
	SS 316L Storage Tank	1	5 KL
	RO1(Reverse Osmosis)	1	2.6 CuMtr/Hr
	RO2(Reverse Osmosis)	1	2.2 CuMtr/Hr
Purified Water	Post UF system	1	2.0 CuMtr/Hr
	ED1(electro-deionization)	1	2.1 CuMtr/Hr
	SS 316L Purified storage tank	1	10 KL
	Ozoniser	1	25 g/hr
MEE	GF-MEE	1	2000 Kg/hr
Boiler	GF-BO	2	4.5 Tons
	GF-BO	1	2.8 Tons
	FF-HWS	3	100 CuMtr/Hr
Hot Water Generator	FF-HWS	1	20 CuMtr/Hr
	GF-CT	3	250 TR

	GF-CT	2	150 TR
Cooling Tower	GF-CT	1	60 TR
Liquid Nitrogen tank	UT-GF-LNS-01	1	13 KL

INSTRUMENT NAME	**MAKE**	**MODEL**
ANALYTICAL BALANCE	METTLER TOLEDO	XPE205D R
MICRO BALANCE	METTLER TOLEDO	XPE26
PRECISION BALANCE	METTLER TOLEDO	XPE1203S
ANALYTICAL BALANCE	SCALE TECH	SAB224CL
PH METER		S400
PH METER/ CONDUCTIVITY METER	METTLER TOLEDO	S400 Bio
GC	AGILENT	7890B
HPLC	AGILENT	1260 Infinity
FT-IR	PERKIN ELMER	SPECTRU M TWO
UV SPECTRO PHOTOMETER	AGILENT	CARY 60
POLARIMETER	ANTON PAAR	MCP 200
LAMINAR AIR FLOW	ICLEAN	N/A
Biosafety Cabinet	ICLEAN	NA
Dynamic passbox	Iclean	NA
STABILITY CHAMBER	NEWTRONIC	NLHC16SI
COOLING CHAMBER	NEWTRONIC	NLCC16SI
PHOTOSTABILITY CHAMBER	NEWTRONIC	NLPS16SI
BOD INCUBATOR CHAMBERS	NEWTRONIC	NLBOD16 SI
HOT AIR OVEN	Meta Lab	NA
AUTO TITRATOR	METTLER TOLEDO	T5

KF TITRATOR	METTLER	T7
GAS FLOW METER	AGILENT	ADM1000
DEEP FREEZER	Haier	DW- 40L262
HOT PLATE	Meta Lab	GMP model
VACUUM OVEN	Meta Lab	GMP
REFRIGETATOR	SAMSUNG	DIGITAL INVERTER
CYCLOMIXER	REMI	CM101
MUFFLE FURNACE	Meta Lab	GMP
WATER BATH	Meta Lab	GMP
VACUUM PUMP	Rocker	NA
PETRI SAMPLING SYSTEM	HIMEDIA	LA367
STERILISATION AUTOCLAVE	PHARMALAB	NA
DECONTAMINATION AUTOCLAVE	MACHIN FABRIK	
HALOGEN MOSITURE ANALYSER	METTLER TOLEDO	HX204
MILLIQ WATER SYSTEM	MERCK MILLIPORE	Elix
Microscope	Olympus	CH20i
Digital colony counter	ESICO	361
Fogger	Spurthi	NA
Dry bath	Rocker	310 Sahara
Hot air oven	Willington Electrolab (india) private limited	NA
Electromagnetic sieve shaker		EMS-8

Manufacturing block

GMP critical computerized systems

The manufacturing and analysis aspects involves the usage of computerized systems. All the computerized systems that are used for manufacturing and analysis shall be tested and calibrated as per the regulatory requirements and GMP compliance. Audit trials, periodical performance/ calibration checks and will be conducted for the respective computerised systems to ensure the adequacy for the operations being used.

DOCUMENTATION:

As part of cGMP requirements, the company is involved in the documentation activity, which provides a means for the company to retain all the records of its activities. The documentation system i.e. initiation, approval and distribution of documents carried out as per defined procedure. Standard formats and instructions are available for preparation of all major documents. The available documents are Specifications and Method of analysis of Raw Materials, Packing Materials, Intermediates and Finished drug substances, Standard Operating Procedures of all departments, Batch Production Records, Packing Record, Analytical Record etc. The documents are retained as per their respective retention period.





Some Photographs of Raw Warehouse Department








Some Photos of Manufacturing block

Handling of rejected materials and products: (SOP No. WH/012, Title: Handling of Rejected Materials)

Any material that is rejected and found not conforming to the requirements or specifications is treated as "Rejected Materials". In such cases, QC affixes 'Rejected 'labels on each such container and rejection note is prepared giving reasons for Rejection. The stocks are moved to an area designated for rejected stocks and kept under lock and key. The rejected material is reprocessed / reworked / disposed as per procedure and documented. Containers are sealed with tamper evident having unique number and the seals details were captured in the packing record for reference.

The SCM informs the vendor of rejection along with reason for rejection. The rejected material then sent back to the vendor or disposed.

QUALITY CONTROL (QC):

The Quality Control facility is well equipped with sophisticated instruments. The objective of Quality Control is to collect analyze various materials such as raw materials, in process, intermediates and Finished Drug Substances as per the existing standard test procedures. QC is authorised to approve / reject the material based on the test results and is independent from manufacturing. Some of the prime activities are as follows.

- All chemical, physical and microbial analysis shall be carried out as per Specification & Method of analysis. Approve or reject raw materials, Packing components, In-process materials, intermediate material and finished drug substances based on the testing and analytical acceptance criteria and predetermined specification.
- Preparation or revision of specification, Analytical Methods and procedures, which directly or indirectly contribute to the identity, strength, quality and purity of the company's products.
- Investigation of non-conforming material.
- Investigate complaints relating to the analytical quality of the company's products.
- Review and retain all records relating to the testing and approval of raw materials, packaging components, in-process materials, intermediate and Finished Drug Substance.
- Approve or Reject the proposed new sources of supply of raw materials and packaging components

- Maintain a stability program, enter results in stability program formats, and make retest date/expiry date recommendations based on the results. Participate in the development, implementation, and maintenance of cGMP & GLP.
- Finished Drug Substance release.
- Method validations, analytical validations and key raw material method validation.
- Calibration of instruments in Quality Control.

Microbiological testing shall be performed in the site for the finished products, facilities and water etc. as per the requirement

Well equipped QA department at Almelo Pharmaceuticals

SELF INSPECTIONS: (SOP No. QA/008, Title: Internal Audits)

Self-Inspections are carried out with the objective of ensuring the implementation and compliance of cGMP. Inspection team from cross-functional department's audit the identified departments as per the schedule for compliance of laid down systems and procedures. Such inspections are carried out as per a defined procedure and frequency.

Self-Inspections is conducted every three months in a year to check the compliance and to lay down procedures / guidelines of Quality Management System and Good Manufacturing Practices. Non-compliance report is given to auditee for which corrective and preventive actions are to be taken. Internal audits shall be performed as per schedule approved by QA. The personnel conducting the audit are trained either externally or internally. Internal audits are undertaken by

qualified personnel who are not directly responsible for the area being audited. Other than QA personnel, individuals from cross-functional areas are selected and trained as internal quality auditors to perform internal auditing. Upon completion of the audit, the audit findings are reviewed with all the respective department heads. The audited departments individually respond to the findings in the audit report and detail about the correction, corrective and preventive actions taken. The corrective and preventive actions are verified in the follow up audit. Effectiveness of the self inspection program and status of completion of actions shall be reviewed timely under management review system.

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