An Industrial Training Report
Of
EVEREST PARENTERALS Pvt. Ltd
(Chhatapipra Bara Nepal)

A Training Report Submitted To EVEREST PARENTERALS

Submitted By: Submitted To,

HARINARAYAN SAH Mr. Rajesh Prasad

ACKNOWLEDGEMENT

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Table Contain

INTRODUCTION

Everest Parenterals Pvt. Ltd. is the first state-of-the-art sterile injectable manufacturing facility in Nepal. The plant is ideally situated in Chhatapipra, Bara, Nepal adjoining to India through its border in Bihar. It is the first plant in Nepal that facilitates manufacturing of Large Volume Parenterals, Small Volume Parenterals, Eye/Ear Drops & Nasal Spray under one roof. It was incepted in 2015 with a vision to provide high quality injectable to the country at low costs making the country self-sufficient in injectable products.

The plant has been setup complying with WHO GMP standards & Norms. The plant is spread across 85,000 sq. ft. of land with over 78,000 constructions. More than 50% of the land has been dedicated to lush green and open space. Our facility includes automated LVP & SVP production facilities, hi-tech 6,000 sq. ft. of Quality Control Laboratory and a dedicated Research & Development facility. To ensure quality and compliance we have very stringent Quality Assurance policies.

Our production capacity of the machineries at plant is:

LVP

PP Bottle Nipple Head/Euro Port/Sterile Port – 2200 bottles/hour
Non-PVC Flexi Bag Container Euro Port/Sterile Port – 2500 bags/hour

SVP

Glass Ampoules – 14000 ampoules/hour
Glass Vials – 7000 vials/hour

OCULAR

3-piece eye/ear drop – 14000 bottles/hour
Nasal Spray with Actuator – 7000/hour

MISSION

To become the leading sterile injectable manufacturing & distribution company in the country.

VISION

To provide high quality affordable injectables, making the country self-sufficient in injectable products.

MOTTO

Ensuring Wellness

PRODUCTS

INJECTABLES

Brand Name: TRAXAREST

Generic Name: Tranexamic Acid Injection BP

Strength: 500mg/5ml

Volume: 5ml

Therapeutic category: Antifibrinolytics

TRAXAREST I.V. Injection is a clear, colorless sterile solution. It contains 500mg/5ml of Tranexamic Acid and it belongs to a group of medications called Antifibrinolytics. It may also use for other conditions as determined by the doctor. This medicine is to be given only by or under the direct supervision of the doctor.

Brand Name: NEOMINE

Generic Name: Neostigmine Injection IP

Strength: 0.5mg/ml

Volume: 5ml

Therapeutic category: Acteylcholinesterase Inhibitors

NEOMINE is a clear, colorless solution. It belongs to a group of medicines called cholinesterase inhibitors. It is used when muscles become abnormally tired and weak (myasthenia gravis).

Brand Name: Granset

Generic Name: Granisetron Hydrochloride

Strength: 1.0mg/ml

Volume: 1ml

Therapeutic category: Anti Emetics

GRANSET I.V./I.M. Injection is clear, colourless sterile solution. It contains 1.0 mg/ml of Granisetron Hydrochloride and it belongs to a group of medications called 5-HT, receptor antagonists. It works by blocking serotonin, a natural substance
in the body that causes nausea and vomiting.

Brand Name: Evaclin

Generic Name: CLINDAMYCIN PHOSPHATE

Strength: 150MG/ML and 300MG/ML

Volume: 2ml And 4ml

Therapeutic category: LINCOMYCIN ANTIBIOTICS

Description: Evaclin is a clear, colorless to almost colorless solution. It contains 150mg/ml of Clindamycin and it belongs to a group of medicines called antibiotics. Clindamycin is usually reserved for the treatment of serious infections, especially when other antibiotics have been unable to clear the infection and when the infection is caused by bacteria that are sensitive to Clindamycin.

Brand Name: GENTAREST

Generic Name: Gentamicin

Strength: 40mg/ml

Volume: 2ml and 10ml

Therapeutic category: Anti-Bacterial; Aminoglycoside Antibiotic

Description: GENTAREST I.V./I.M. Injection is clear and colourless to pale yellow solution. It contains 40mg/ml of Gentamicin base and it belongs to a group of medicines called Aminoglycoside Antibiotic.

Brand Name: DOPAMID

Generic Name: DOPAMINE HYDROCHLORIDE

Strength: 40mg/ml

Volume: 5ml

Therapeutic category: Inotropic Agents

Description: Dopamid is a clear, colorless, almost colorless to pale yellow solution. It contains 40mg/ml of Dopamine Hydrochloride and it belongs to a group of medicines called Inotropic agents.

Brand Name: EVACAINE

Generic Name: LIDOCAINE HYDROCHLORIDE

Strength: 2% W/V

Volume: 30ML

Therapeutic category: LOCAL ANESTHETICS

Description: EVACAINE 2% is a clear, colorless sterile solution. It contains 20mg/ml of Lidocaine Hydrochloride and belongs to a group of medicines called Local anesthetics. It is used to produce local anesthesia (numb a specific area) and stop pain being felt in the area of the body where it is administered. Also, control fast or abnormal heartbeats that are experienced after a heart attack.

Brand Name: LFXN 0.5 EUROFLEX

Generic Name: Levofloxacin

Strength: 0.5%W/V

Volume: 100ml

Therapeutic category: Anti-Bacterial; Fluoroquinolone Antibiotic

Everest Parenterals has 8 Department.

1. Quality Assurance (QA)
2. Quality Control (QC)
3. Formulated and Development (F & D)
4. Small Volume Parenterals (SVP)
5. Large Volume Parenterals (LVP)
6. Store (RM, PM, FB)
7. Engineering and Utility
8. Admin (HR, Procurement, Account & Logistic, HK)

QUALITY ASSURANCE

QA department is well-handled by professional staff who have years of experience in this field. It ensures that the product manufactured adheres to specific standards and strives to continuously improve results and eliminate error.

QUALITY ASSURANCE DEPARTMENT:

Quality Assurance (Q.A) is the sum total of organized arrangements made with the object of ensuring that product will be of the quality required by their intended use. Quality assurance is the systematic monitoring and evaluation of the various aspects of a project, service or facility to maximize the probability that minimum standards of quality are being attained by the production process. QA cannot absolutely guarantee the production of quality products.

In ENVOY, there was a pharmacist to maintain the reliability at every stage of manufacturing process starting from Research, Clinical studies, Quality Control, Production, Distribution and provides information on appropriate use, and analyses safety and information of the products. This department assists in the strategic direction and development of Quality Systems, standard operating procedures and document control programs, to ensure with the company policies and regulatory requirement.

Role of Quality Assurance in industry

Temperature check

Humidity checking

Line clearance (at different stages, in line clearance our focus is on cleanliness proper identification of product batch No. packing procedure, product labeling)

Stability testing

Maintain record

Dispatch testing

Handling of market complains • Dispensing checking

In-process testing

SOP designing

Workers training

Validation

Self inspection/internal audit

Art work

Market return

OVERVIEW OF QA'S ROLE:

- Development Stage – During R&D, checking the qualification of raw material, vendors, testing methods, validation, document control, equipment calibration and operating procedures, personnel recruitment and training, data recording, clinical trials, formulation of API batches, and more.
- Manufacturing Stage – These are a few examples of the QA unit's role during production:

- Preparing, approving and monitoring the implementation of key documents (Quality Policy and Objectives, Quality Manual, etc.).
- Ensuring that specifications and test procedures for raw materials, packing materials, in-process testing, APIs, stability testing, etc. are all in place.
- Reviewing training records to check if on-the-job and induction training is taking place according to the schedule and whether QC (Quality Control) analysts are being validated.
- Ensuring that planned/unplanned changes or deviations are documented, reviewed and analysed, and recommending studies, tests or validation activities to be performed.
- Initiating, documenting and investigating market returns, reprocessing (for API batches) or destruction (for finished batches), and informing regulatory authorities about defects found, if any, after distribution.
- Reviewing and approving manufacturing records and QC testing data before any intermediate, API or finished batch is released, as well as periodic trending of this data.

There are 4 room in the QA Department

1 Office Room

2. Document Room

3. Stability Room

4.Sample Room

1. Office Room:-

In this room , there are QA office , QA head , QA senior Executive , Executive , Junior Executive.

They maintain allthe record of manfacing , Testing , Packaing and Raw material.

They QA office also prepare Batch Manufacturing Record (BPR) and Batch packagimg Record (BPR) . It also preparer and maintain sop for the company and for all department .

The sop for QA department is called Master copy , and sop for other all departement is called controlled copy .

They also check all the process , material manufactuing , packaing and dispering record.

B. Document Room

In this Room , all the records of the products are maintain in a file .

All the Records of Raw material and manufacture Records , Quality Testing Records , packaging Records are maintained in a file and and are arranged in a formate.

C. Stability Room

I this Room , the product are kept in a machine called HMI . The product are kept in two types of temperature called Real time Stability and Accelerated Stability .

1. For Real time stability

   Temperature 30 ± 2°C and 75 ±5 RH

2. Accelerated Stability

   Temperature 40 ±2°C and 75± 5 RH

D. Control Sample Room

In this room all the Sample Products are kept in a room. They are kept in a room more than of their sefl life or expiry date.

GMP recommended by agencies that control authorization, licensing for manufacture, sale offood, drug products, and active pharmaceutical products. These guidelines provide minimumrequirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of Good manufacturing practices (GMP) are the practices required in order toconform to the guidelines high quality and do not pose any risk to the consumer or public

cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Foodand Drug Administration (FDA). GMPs provide for systems that assure proper design, monitoring,and control of manufacturing processes and facilities. Adherence to the cGMP regulations assuresthe identity, strength, quality, and purity of drug products by requiring that manufacturers ofmedications adequately control manufacturing operations. This includes establishing strongquality management systems, obtaining appropriate quality raw materials, establishing robustoperating procedures, detecting and investigating product quality deviations, and maintainingreliable testing laboratories. This formal system of controls at a pharmaceutical company, ifadequately put into practice, helps to prevent instances of contamination, mix-ups, deviations,failures, and errors. This assures that drug products meet their quality standards.

Validation

Validation is a process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in production or testing maintains the desired level of complianceat all stages. In Pharma Industry it is very important apart from final testing and compliance of product with standard that the process adapted to produce itself must assure that process willconsistently produce the expected results. Here the desired results are established in terms ofspecifications for outcome of the process.

Types of validation

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Process validation

Process Validation is the analysis of data gathered throughout the design andmanufacturing of a product in order to confirm that the process can reliably output products of a determined standard. Regulatory authorities like EMA and FDA have published guidelines relating to process validation. The purpose of process validation is toensure varied inputs lead to consistent and high quality outputs. Process validation is anongoing process that must be frequently adapted

as manufacturing feedback is gathered.Process validation can be broken down into 3 steps: process design, process qualification,and continued process verification.

Cleaning validation

Cleaning validation is the methodology used to assure that a cleaning process removesresidues of the active pharmaceutical ingredients of the product manufactured in a piece ofequipment, the cleaning aids utilized in the cleaning process and the microbial attributes.All residues are removed to predetermined levels to ensure the quality of the next productmanufactured is not compromised by waste from the previous product and the quality offuture products using the equipment, to prevent cross-contamination and as a GMPrequirement.

9.4 CAPA (Corrective Actions and Preventive Actions)

CAPA is a fundamental management tool that should be used in every quality system.

Corrective Actions

A corrective action is a term that encompasses the process of reacting to product problems,customer complaints or other nonconformities and fixing them. The process includes:

Reviewing and defining the problem or nonconformity.

Finding the cause of the problem.

Developing an action plan to correct the problem and prevent a recurrence

Implementing the plan.

Evaluating the effectiveness of the correction.

Preventive Actions

A preventive action is a process for detecting potential problems or nonconformances andeliminating them. The process includes:

Identify the potential problem or nonconformance.

Develop a plan to prevent the occurrence.

Implement the plan

Review the actions and the effectiveness in preventing the problem

9.5 Deviation

Deviations are measured differences between observed value and expected or normal value for a process or product condition, or a departure from a documented standard or procedure.

A deviation may occur during sampling and testing, raw materials- and finished productacceptance and manufacturing. Deviations may also be triggered by customer complaints orcomments when the customer company's standards do not meet critical attributes as delivered percertificate.

9.6 Change control

The change control program evaluate all changes that could affect the production and control ofthe drug product, intermediate or API. It is the most critical element in the overall qualitymanagement of pharmaceutical industry.

9.7 Recall & withdrawal

Recall

Recall means removal from market of specific batch/batches of product from further scale or use to protect public health and well being.

Withdrawal -

It refers to removal of a product from market from sale or use that does not violate regulation administered by the FDA

9.8 Qualification

When this approach is related to a machine or equipment, rather than Validation, this is referredas Qualification. Qualification is part of, but not limited to, a validation process, which in turn can be divided into Installation Qualification (IQ), Operation Qualification (OQ), or PerformanceQualification (PQ).

9.9 Data Integrity

Data integrity refers to the complete, consistency and accuracy of data.

ALCOA in data integrity

Attributable: Traceable documentation.

Legible: Readable, understandable, informatics.

Contemporaneous: Current dated documentation.

Original: Authentic or approved format documentation should be done

Accurate: documentation should be

QUALITY CONTROL

Quality has always been the topmost priority for Everest Parenterals Pvt. Ltd. Our QC team follows a rigorous quality check policy to ensure that no quality is compromised at any cost. The quality check is performed for all the raw materials, packaging materials and after each stage of production.

The QC laboratory is well-equipped with advanced machinery and equipment like HPLC, FTIR, UV Visible Spectrophotometer, etc.

HIGHLIGHTS OF QC LAB

- Separate Change Room for microbiology and quality control lab.
- The total lab is equipped with modular furniture containing a granite top for instruments and an alpha ICA benchtop for wet chemistry.

- Separate room is provided for HPLC and FTIR.
- The lab is equipped with an online UPS system.
- Separate room for hot instruments.
- Separate two instrument rooms for major and minor instruments.
- Separate wet chemistry lab with alpha ICA furniture (acid resistance benchtop).
- Two chemical cabinets (for chemical storage), connected to an exhaust duct to ensure the safety of the analyst.
- Fume hood with water tap, light and exhaust is provided to keep the lab safe from hazardous fumes.
- Equipped with separate eyewash and safety shower to prevent dangerous accidents.
- Sufficient qualified manpower working in the lab with a separate documentation room.

Quality Control test for material by Q.C department. For different materials and dosage form different tests are performed, following of them are

⚫ Test for Raw Material

For testing of raw material following test are performed according to SOP or referenced set by supplier

Description or Physical appearance (crystalline, powder, smell, color,)

Solubility (solubility is check by dissolving in alcohol, chloroform or in water if substance organic in nature and non polar t will dissolve in alcohol and chloroform and if substance is inorganic n polar in nature will easily dissolve in water)

Identification (identified by using FTIR, TLC, UV spectrometer)

pH (checked by pH meter pH should be within range as recommended by official books)

Viscosity (viscosity is checked by viscometer and it should be within range As recommended by official book)

Assay (percentage purity of sample is checked by analyzing the sample by using U.V spectrometer or HPLC, FTIR but mostly used apparatus is U.V spectrophotometer)

LOD/ Loss on Drying

Wt. of empty Petri-dish = A

Wt. of Petri-dish+Sample = B

Wt. of sample =B-A=C

After drying at 105C for 30 minutes wt. of Petri-dish + sample = D Difference between wt. before drying and after drying 30< =B-D=E

% LOD Diffrence

Wt. of Sample E ==x100=E

INSTRUMENTS USED IN THE QC DEPARTMENT OF EVEREST PARENTERALS

UV Spectroscopy:- UV-Vis spectroscopy is an analytical technique that measures the amount of discrete wavelengths of UV or visible light that are absorbed by or transmitted through a sample in comparison to a reference or blank sample.

Principle:- The Principle of UV-Visible Spectroscopy is based on the absorption of ultraviolet light or visible light by chemical compounds, which results in the production of distinct spectra.

FT-IR SPECTROSCOPY:- Fourier-transform infrared spectroscopy is a technique used to obtain an infrared spectrum of absorption or emission of a solid, liquid, or gas. An FTIR spectrometer simultaneously collects high-resolution spectral data over a wide spectral range.

Principle:- infrared spectroscopies act on the principle that when infrared (IR) radiation passes through a sample, some of the radiation is absorbed. The radiation that passes through the sample is recorded.

INSTRUMENTS IN Q.C DEPARTMENT:

Different instruments are use for testing in Q.C department:

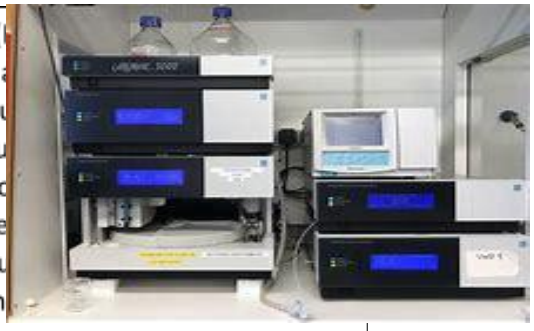
Fourier Transform Infrared Spectrophotometer.

UV/visible Spectrophotometer.

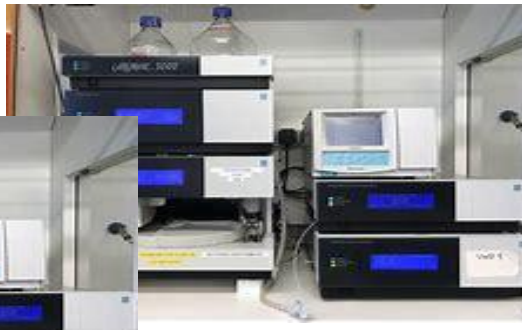
Ultraviolet-visible spectroscopy or ultraviolet-visible spectrophotometry (UV-Vis or UV/Vis) refers to absorption spectroscopy or reflectance spectroscopy in the ultraviolet-visible spectral region. Ultraviolet-visible (UV-VIS) spectroscopy is an analytical method that can measure the analyte quantity depending on the amount of light received by the analyte.

High Performance Liquid Chromatography.

High-performance liquid chromatography (
as high-pressure liquid chromatography, is
chemistry used to separate, identify, and qu
mixture. It relies on pumps to pass a pressu
containing the sample mixture through a co
adsorbent material. Each component in the
differently with the adsorbent material, cau
the different components and leading to th
components as they flow out of the column.



High-performance liquid chromatography (HPLC), formerly referred to as high-pressure liquid chromatography, is a technique in analytical chemistry used to separate, identify, and quantify each component in a



High-performance liquid chromatography (HPLC), formerly referred to as high-pressure liquid chromatography, is a technique in analytical chemistry used to separate, identify, and quantify each component in a mixture. It relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material. Each component in the sample interacts slightly differently with the adsorbent material, causing different flow rates for the different components and leading to the separation of the components as they flow out of the column.

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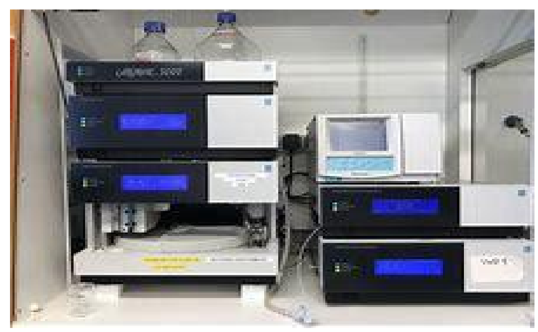

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Automatic Polarimeter.

Thin Layer Chromatography. Magnetic Stirrer.

Viscometer.

Sonication Bath.

Melting Point Apparatus.

pH / Conductivity meter

Analytical Balance.

Desiccators

R&D

Everest Parenterals is one of the exceptional companies in Nepal that has an independent Research & Development department in its plant. Provided with its own lab equipment and machinery, the R&D department is self-reliant in carrying out its operations.

Our R&D team is in continuous pursuit of developing new formulations and improving the existing ones. The team works in a proper environment fostering excellence and innovation, which are most essential to develop complex and challenging first-time combination products.

We spare no effort in improving the lives of our people. Our pharmacists are passionate about exploring new innovative ways to mitigate the health problems of people.

HIGHLIGHTS OF R&D

Self-contained Area with dedicated AHU.

Complete R&D setup with own analytical and formulation lab.

Furnished with GMP model machines that are capable of manufacturing all types of non-sterile dosage forms.

Complete lab setup with dedicated HPLC (DAD detector) for testing of trials and stability batches.

Equipped with multipurpose R&D machine, single machine capable of performing 20+ different tasks.

Fully SS 304 and 316 furnished.

Works with the concept of quality design.

RESEARCH & DEVELOPMENT DEPARTMENT:

EVEREST PARENTERALS has dedicated research teams at both national and international level. Their R&D team has all the necessary skills and equipment to formulate and produce even unique and new combinations of medicine.

There is a R&D department in ENOY which worked in discovering new knowledge about products, processes, and services and then applying that knowledge to create new and improved products, processes and services that fill market needs.

They used following apparatus:

Small Volume Parenterals (SVP)

In SVP 3 types of products are manufactured

1.Vials

2. Ampoule

3. Opthalmics Drops

In SVP, there is 3 sections

1. Manufacturing
2. Filling
3. Packaging

1. Manufacturing

   For manufacturing of liquid products in SVP, 3 three types of tanks are availabe on the bassis of volume.

   a. Ampoule Tank = 100 litres capacity
   b. Drop Tank = 200 litres capacity
   c. Vials Tank = 300 litres capacity

2. Filling

   Filling of Ampoule has various stages

   a. Washing of Ampoule Containers

      - R.C Water
      - R.C Water
      - Compressed Air
      - Purified Water
      - Purified Water
      - Compressed Air

- Water for Injection
- R.C Water (outer)
- Compressed Air (outer)
- Compressed Air

Then it is forwarded to Sterilizing

Machine Name:- Sterilizing & Depyrogenation tunnel

MFG:- Klenzaids

Capacity:- 282 Ampoule/min

It consist :-

- Drying Zone
- Heating Zone
- Cooling Zone
- Stabilizing Zone

After washing and sterilizing the container it is forward to filling machine .

For ampoule filling

- First 8 needle contain Nitrogen gas.
- Second 6 needle contain liquid product.
- Third 8 needle contain Nitrogen gas.

After filling, with fire of LPG + Oxygen , the ampoule are sealed and sent for packaging .

Packing

Type of packing.

- Primary packaging – container
- Secondary packaging – Mono cartoon
- Tertiary packaging – sheeper

For packaging of vials .

Vials are rubbed with clothes before labeling it . After rubbing outer surface , labeling for ampoule

Label with labeling machine

Inspection of proper print and sealing pack in factory

Increase in mono cartoon

Pack with shank machine – in plactic

Pack in cartoon

Keep in store room

Ready to Dispactch

LVP

ENGINEERING

Engineering department play's an important role in pharma company;

- They are responsible for designing the facilities, installation, startup, maintenance andup gradation and also providing required utilities per cGMP requirements.
- They are also responsible for regular smooth operation of the plant. The activitiesare generated centrally and distributed to the units as per requirements.

Engineering Department Responsibilities

1. Maintain the facility, equipment and upgrade facilities.2.
2. To prepare execute preventive maintenance, calibration, validation schedule of HVAC.3.
3. To maintain the central utility equipment so that required can be provided to plans.4.
4. To execute the project in given time line.5.
5. To maintain the BMS for the plant as per requirements.

HVAC (Heating, Ventilating and Air Conditioning)

AHU (Air Handling Unit)

Calibration

Utilities

HVAC

It is a technology of indoor and vehicular environmental comfort. Its goal is to provide thermalcomfort and acceptable indoor air quality. Its working and management is based on principlesof thermodynamics, fluid mechanics and heat transfer. Refrigeration is also sometimes added asHVAC&R. it is basically done to control temperature, oxygen replenishment, removal ofmoisture, odors, smoke, heat, dust, air borne bacteria, carbon dioxide and other gases.

AHU

It is a device used to regulate and circulate air as part of a heating, ventilating and air-conditioningsystem. It is usually a large metal box containing blower, heating or cooling elements, filter racks orchambers, sound attenuators and dampers. Air handlers usually connect to a ductwork

Ventilation system that distributes the conditioned air through the building and returns it tothe AHU.

Calibration

Calibration is the process of finding relationship between two quantities that are unknown(when the measurable quantities are not given a particular value for the amount considered orfound a standard for the quantity). The purpose of calibration is for maintaining the quality ofmeasurement as well as to ensure proper working.

Utilities

These are the primary resource or source which are provided to a system or machine to convertinto power or secondary utility.

Utilities are necessary of product and humen comfort.

- Electricity
- Warm water (light green pipe)
- Chilled water (dark green pipes)
- Compressed air (white pipes)
- Portable water (blue pipes)
- Steam (silver pipe)

HUMAN RESOURCE

An enthusiastic & well-spirited team of people is the life force of Everest Parenterals. People working as a team, skill-based support unit for generating ideas, knowledge of modern technology, research & development; all contribute to improvement and development of the company.

The Human Resource Department of Everest Parenterals prepares the HR strategies and helps the organization by forecasting the HR needs, matching demand and supply, selecting the right human resources at the right place at the right time. Moreover, it provides them with the necessary training & skills and motivates them for better career opportunities for the better performance of the individual and company as well. The company strongly supports employment creation within the country thereby creating opportunities for highly qualified and experienced personnel as well as semi-skilled candidates.

FINISH GOOD STORE:

Finished products are stored in this area. Temperature and humidity is controlled here to assure stability and effectiveness of products. Products that require cold storage are stored in refrigerator. Finished good received report is also signed.

After passing Q.C tests, quality products after manufacturing and packing are kept here. And then products are supplied to different institutes etc.

Today Everest parenteral Pvt Ltd. Products are being promoted & sold in every part of Nepal.

DISCUSSION:

Everest Parenteral enhanced understanding of my academic knowledge and skills. It indeed polished my knowledge and experience. Classroom studies are confined only to books and

theoretical learning majorly. Application of these theories and lectures delivered in classrooms differ a little from the specifically set format.

Through this internship, I not only got the opportunity to experience but I also learnt the applications of these theories in actual the application. I got to observe the whole working environment of pharmaceutical industry & the important aspects regarding the production of high quality pharmaceuticals & carrying out important quality control tests to ensure that all the procedures carried out during production are according to GMP.