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REVIEW ARTICLE

A Study on Summer Pharmaceutical Industrial Training

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ABSTRACT

Practical exposure of industrial operation, set up and management is very crucial part in learning and to be skilled for competitive and global demand in pharmaceutical industry. To fulfill these objectives industrial training is mandatory for the award of B. Pharm. Degree. Being a student who wants to mark in industrial field, the best place to gain practical understanding of production is to do summer training in the production department of Pharmaceutical Industry which can be regarded as one of the most dynamic industry in India. The student have proud to work as an internee in pharmaceutical industry and the experience will surely help me in future assignments as a marketing professional. The absolute guidance and concern of higher management of the staff of all departments especially the marketing department facilitated in making my summer Training a wonderful learning experience in all aspects. Summer training is given for six weeks was based on industrial project. Through these projects, the trainee become able to get direct interaction with different chemists along with staff of Production, Q.A., Q.C. and Logistics, Administration and Human Resources Departments of pharmaceutical industry.

KEYWORDS

Formal training, Industrial training, Q.C., Q.A., Quality policy of company

INTRODUCTION

The pharmaceutical industry is a professionally managed and a dynamic organization with decades of experience in pharmaceutical industry. Since our inception, it has been manufacturing good quality pharmaceutical products. With a desire of providing opportunities for better life, it works very hard to bring quality drugs to the customers. Company has instilled a level of trust and confidence amongst their clients by supplying the best quality products. Backed by our unmatched infrastructural facilities and qualified team of pharmacists, Company always occupied a premium position in the diary of their clients.

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A. Objective

The main objective of any industry is to bring about the conversion of raw material, the manufacture of good & the provision of service.

B. Benefits

The pharmaceutical industry has been an easy target for critics over the years. There is a perception that "Big Pharma" is strictly out for profit and that pharmaceutical companies will stop at nothing to line the pockets of their shareholders. The reality is this: Many of these drugs are saving lives and helping people live the pharmaceutical industry develops and produces products that help treat a variety of diseases, saving millions of lives and helping people suffering from diseases and illnesses to recover and lead more productive lives. The

pharmaceutical industry develops drugs that treat every type of condition imaginable, such as influenza, sexually transmitted diseases, cardiovascular disease, diabetes, hepatitis, Parkinson disease and cancer. Many of these are devastating and life-altering diseases, and these products help keep patients alive longer, happier, healthier lives.

C. Quality Policy of Company

The Company is committed to Total Quality Management. The raw and packaging materials are procured either from approved vendors or reliable resources. These are received at the stores with all necessary documents, which are properly scrutinized. The Material received is first stored in the Quarantine area and label indicating "QUARANTINE" is affixed on all the containers of the lot received. The Material received is immediately recorded into the stock records. Sampling is done by the Quality Control Department in accordance with the SOPs for drawing samples for various materials. Samples are tested by the Quality Control Department to confirm compliance to the prescribed specifications. The materials approved by the Quality Control Department Rejected materials are promptly returned to the supplier or are destroyed Destruction in presence of Q.A. Person). The labels of "APPROVED" and "REJECTED" are controlled by Quality Control Department Approved materials are dispensed to production first in first out (FIFO) basis. Active ingredients are dispensed in a separate dispensing room .Production is carried out under supervision of FDA approved technical staff, as per the prescribed processes and procedures. There are prescribed provisions for in-process checks by the quality control and production department. The particulars of in-process checks carried out and the results thereof are entered in Batch Manufacturing Records (BMR). The bulk is tested for compliance with the prescribed specifications, before these are filled in the primary container. The finished products are tested as per the specifications. All equipment in the manufacturing area are regularly cleaned, maintained and validated. The Company has a well-equipped quality control laboratory. The instruments in the quality control laboratory are calibrated at regular intervals as per the SOPs. Proper records are maintained for all calibrations. Self-inspections are carried out regularly by the internal audit team. There is well- defined procedure for handling product complaints. The quality assurance department (Q.A.) scrutinizes each BMR. Products are released for dispatch only after Q. A. Approved

FORMAL TRAINING

A. Training and Development

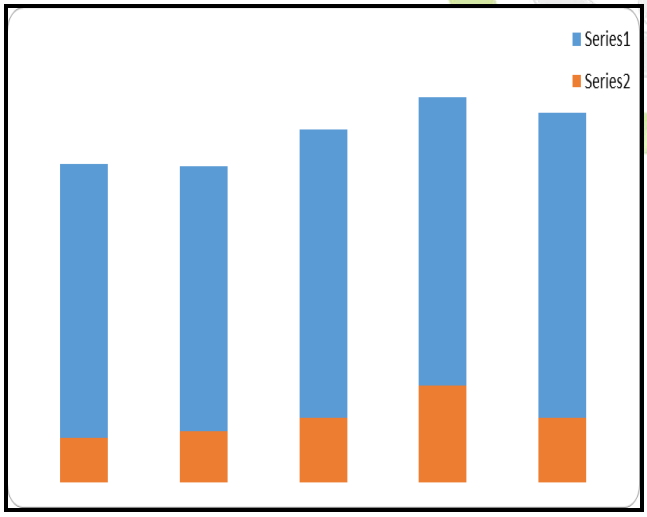
The function of Human Resources is not only to attract the best qualified and most talented candidates, but also to provide a stimulating and challenging environment in which employees can pursue personal and professional growth as well as a long term career. PIL spends millions on employee training and development. We believe that our employees provide a competitive advantage and to maintain that advantage, constant training and development is essential.

Training takes many different forms – from on the job training to formal educational programs – we have a broad spectrum of training and development opportunities for qualified employees.

B. Conducting Needs and Knowledge Assessments

A training needs assessment and a pre training knowledge and skills assessment are required to help plan an effective training program. The needs assessment should encompass the overall working environment, including the supervisory structure and the level of employee motivation. Pharmaceutical management training will be effective only if all areas of the pharmaceutical supply system are assessed frankly and carefully.
A knowledge and skills assessment evaluates the participants' level of prior knowledge, as well as previous training and experience, in the area of interest. The results of this assessment are used to develop the training learning objectives, and ultimately, the content. The optimal method depends on the goals of the assessment and the cadre of the individuals being assessed. A knowledge assessment can be based on

observation of a worker performing routine duties. This review uncovers both strengths and weaknesses, but the presence of an observer may influence the behavior observed. For example, a clinical worker examining a patient is likely to be more thorough than usual if someone is watching. Interviews with supervisors, administrators, users of services, and workers can help determine where performance problems might exist and what skills need to be taught or improved. If workers fear reprisals from management, reassurances about confidentiality of information will be necessary to obtain good data. In some situations, a training needs analysis can be done by conducting a group interview in which the staff are invited to identify competencies in terms of knowledge, attitudes, and skills. Staff members rate themselves on a graph in relation to each of a set of competencies. Exit interviews with workers leaving their jobs can also be useful. Finally, interviews with users of the services can help in assessing levels of satisfaction. Analyses of job and task descriptions may reveal special training needs. Self-administered, anonymous questionnaires for both managers and workers can also be valuable.



1-Leadership skill 2-Managing skill 3-Interperson skil 4-problem solving skill 5-Team work skill

Figure 1: Skill Obtain During Training

INDUSTRIAL TRAINING

during the training a student gain the knowledge of manufacturing process, material use in process, machines and tests in following department:

A. Production Department

Mostly Solid Dosage Forms Specially tablets and liquid preparation are manufactured In pharmaceutical company.

According to IP pharmaceutical tablets are solid & biconvex discs, prepared by containing a drug or a mixture of drugs with or without diluents & Powders are finely divided particles.

In pharmaceutical company various type of tablets are manufactured like:

- Sugar coated tablets
- Film coated tablets
- BI-layered tablets
- Multiple coated tablets.

Type of coating	Material used
Sugar coating	Shellac
Film coating	Hydroxyl Propyl Cellulose, PEG etc
Enteric coating	Shellac, Cellulose, Acetate Phthalate

For these productions they required specific type of:

1. Diluents-sucrose USP powder, Sorbitol, calcium sulphate dehydrate, dextrose.
2. Binder Adhesives-starch paste, glucose, Sorbitol.
3. Disintegrates-starch.
4. Lubricates-talc, steric acid, PEG.
5. Glidants-corn starch, silica derivatives.
6. Colorants & Flavoring Agents

Evaluation of Tablets

Tablets are evaluated for their chemical characteristics like potency, content uniformity & purity & physical characteristics like:

- Weight & weight variation.

- Hardness
- Thickness
- Friability – friability apparatus
- Disintegration test
- Dissolution test – Dissolution apparatus.

Machines

1. Mechanical sifter
2. Multimill
3. Mass mixer
4. Fluidized Bed Dryer
5. Coating pan
6. Single rotatory 35 station machine
7. Tablet Blister packaging machine
8. Tablet strip packaging machine
7. Powder filling machine

B. Quality Control

Quality control can be defined as day to day control of quality within the company. They are responsible for the acceptance or rejection of incoming raw material, packing components and finished products, for the myriad of in process tests and inspections, to assure that system are been controlled and monitored for the approval and rejections of complete dosage.

QC is the essential operation of Pharma Industry. Drugs must be marketed as safe and therapeutically active. Various analytical and sophisticated methods are being developed for the evaluation of new drugs & for already existing ones.

QC refers to characterization of a product from both Qualitative and Quantitative point of view.

The QC in Pharma Industry is responsible to design, test & Produce Dosage Forms which provide quality, purity, stability, safety, uniformity of contents & physiological availability to consumer.

Quality Control Result From:-

1. Team Work
2. Analytical testing of raw materials
3. Analytical testing of packing materials
4. Analytical testing of finished products
5. Sampling under hygienic conditions
6. Monitoring of Temperature in Q.C

The quality control function in an organization normally consist of at least three primary units-

- Analytical control
- Microbial control
- Packaging control

Instruments

- Tablet Hardness Tester.
- Friability Apparatus
- Karl-Fischer Instrument
- Melting Point Apparatus
- Vernier Caliper
- Micrometer
- Weighing Balance.
- pH meter
- U V spectrometer
- Digital disintegration test apparatus
- Digital dissolution test apparatus
- Autoclave
- Incubator
- Laminar Flow Chamber
- Vacuum oven
- Hot air oven
- UltraSonifier

Quality Control of Tablets

General Appearance

The general appearance of a tablet, its identity and general elegance is essential for consumer acceptance, for control of lot-to-lot uniformity and tablet-to-tablet uniformity. The control of general appearance involves the measurement of

size, shape, colour, presence or absence of odour, taste etc.

Size & Shape

It can be dimensionally described & controlled. The thickness of a tablet is only variables. Tablet thickness can be measured by micrometer or by other device. Tablet thickness should be controlled within a ± 5% variation of standard value.

Unique identification marking

These marking utilize some form of embossing, engraving or printing. These markings include company name or symbol properties:

Color distribution must be uniform with no mottling. For visual color comparison compare the color of sample against standard color.

Hardness and Friability

Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shakes of handling in manufacture, packaging and shipping, product code, product name etc.

Hardness generally measures the tablet crushing strength. The strength of a tablet was determined by following ways;

(a) By cracking the tablet between 2nd and 3rdfingers with the thumb acting as a fulcrum. If there is a sharp snap, the tablet is an acceptable strength.

(b) Tablet hardness can be defined as the force required breaking a tablet in a diametric compression. In this test the tablet is placed between two anvils, force is applied to the anvils, and the crushing strength that just causes the tablet to break is recorded. Generally used Hardness testers are:

(1) Monsanto Hardness Tester

(2) Storm-Cobb Tester

(3) Pfizer Tester

(4) Erweka Tester

(5) Schleuniger Tester

Hardness for compressed tablet is 5 to 8 kg.

Friability of a tablet can determine in laboratory by Roche friabilator. This consist of a plastic chamber that revolves at 25 rpm, dropping the tablets through a Distance of six inches in the friabilator, which is then operate for 100 revolutions. The tablets are reweighed. Compress tablet that lose less than 0.5 to 1.0 % of the Tablet weigh are consider acceptable.

Weight Variation test (U.S.P.)

Take 20 tablet and weighed individually. Calculate average weight and compare the individual tablet weight to the average. The tablet pass the U.S.P. test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Content Uniformity Test

Randomly select 30 tablets. 10 of these assayed individually. The Tablet pass the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labeled drug content and the 10thtablet may not contain less than 75% and more than 125% of the labeled content. If these conditions are not met, remaining 20 tablets assayed individually and none may fall outside of the 85 to 115% range.

Disintegration Test (U.S.P.)

The U.S.P. device to test disintegration uses 6 glass tubes that are 3" long; open at the top and 10 mesh screen at the bottom end. To test for disintegration time, one tablet is placed in each tube and the basket rack is positioned in a 1-L beaker of water, simulated gastric fluid or simulated intestinal fluid at 37 ± 20 C such that the tablet remain 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker in their downward movement.

Move the basket containing the tablets up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute. Floating of the tablets can be prevented by placing perforated plastic discs on each tablet.

According to the test the tablet must disintegrate and all particles must pass through the 10 mesh

screen in the time specified. If any residue remains, it must have a soft mass.

Disintegration time: Uncoated tablet: 5-30 minutes Coated tablet: 1-2 hours.

Dissolution Test (U.S.P.)

Two Set of Apparatus

Apparatus 1

A single tablet is placed in a small wire mesh basket attached to the bottom of the shaft connected to a variable speed motor. The basket is immersed in a dissolution medium (as specified in monograph) contained in a 100 ml flask. The flask is cylindrical with a hemispherical bottom. The flask is maintained at 37±0.50C by a constant temperature bath. The motor is adjusted to turn at the specified speed and sample of the fluid are withdrawn at intervals to determine the amount of drug in solutions.

Apparatus 2

It is same as apparatus-1, except the basket is replaced by a paddle. The dosage form is allowed to sink to the bottom of the flask before stirring. For dissolution test U.S.P. specifies the dissolution test medium and volume, type of apparatus to be used, rpm of the shaft, time limit of the test and assay procedure for. The test tolerance is expressed as a % of the labeled amount of drug dissolved in the time limit.

Dissolution testing and Interpretation can be done in three stages:

Stage 1: Six tablets are tested and are acceptable if all of the tablets are not less than the monograph tolerance limit (Q) plus 5% else failed.

Stage 2: Another six tablets are tested. The tablets are acceptable when 6 tablets are taken, test individually, Avg. weight 12 tablets is greater or equal to but no one less than (Q-15) % If the average of the twelve is greater than or equal to Q and no unit is less than (Q-15) % if failed.

Stage 3: Another 12 tablets are tested. The tablets are acceptable if the average of all 24 tablets is greater than or equal to Q and if no more than 2 tablets are less than (Q-15) %.

C. Quality Assurance

Pharmaceutical quality assurance is a dynamic process, a state of mind or an understanding of the regulations and guidance relating to the development and manufacture of pharmaceutical products. Quality Assurance is a constituent of quality management riveted to assure, generate precise and reliable results on all lab activities that are undertaken. Drugs that are marketed must be safe and therapeutically active. Performance should be consistent and predictable. Or it can be defined as the sum of all activities and responsibilities required to ensure that the medicine that reaches the patient is safe and effective.

The System of Quality Assurance-This department can be divided into four major areas: production, quality control distribution, and inspections.

QA ensures the arrangements made for the manufacture, supply and use of the correct starting and packaging materials.

1. Any deviation from the written production and process control procedures which are followed in the execution of various production and process control functions shall be reported investigated and recorded by the quality department.
2. Deviations from the established time limits for the completion of each phase of production shall be justified and documented by the assurance dept.
3. All the activities involved in the manufacturing process, in-process control and bulk testing shall be approved by the Q.A. dept.
4. All necessary control on intermediate products and any other in-process controls and validations are carried out by the dept.
5. Quality improvement plans.
6. Validation and Technology Transfer.

7. Review of stability date and shelf life of products.
8. Quality team frequently conduct periodic GMP training to personnel at all levels of the organization.

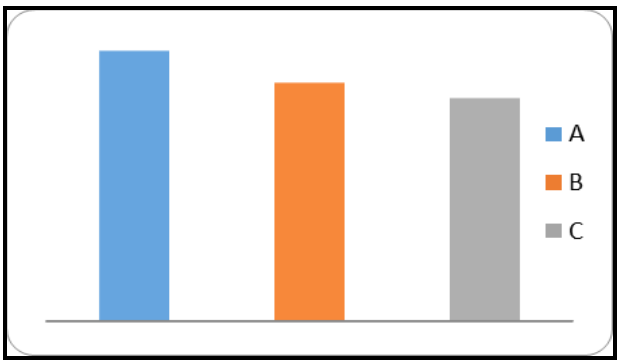


Figure 2: **A** denotes knowledge obtained of machine operating procedure, climate, material used and method in production department. **B** denotes knowledge obtained of testing procedure and apparatus in Q.C. department. **C** denotes knowledge obtained in Q.A. department.

CONCLUSION

The study showed all skills obtained in industrial training by students. This article also showed knowledge of method, machines and procedure used in different department gained by students. The industrial environment increases skill and performance of students.

RESULT

After study on industrial training the result show the requirement of summer pharmaceutical industrial training necessary for pharmacy students for increases skill and future brightness in pharmaceutical field.

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