Assessment of Quality Testing and Drug Approval Process Before Dispatch for Medicines Under Supply Chain System of Punjab Health System Corporation

By

Prashant Vaishnav

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2016-2018

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TO WHOMSOEVER MAY CONCERN

This is to certify that **Prashant Vaishnav** student of MBA Pharmaceutical Management from The IIHMR University, Jaipur has undergone Dissertation training at **Punjab Health System Corporation,** Punjab from 5th February to 4th May 2018

The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

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No. PHSC/QA/18/ 1594 Dated 1.5.18

TO WHOM IT MAY CONCERN
CERTIFICATE OF DISSERTATION COMPLETION

This is to certify that Mr. Prashant Vaishnav student of MBA in Pharmaceutical Management, IIHMR Jaipur has successfully completed three months dissertation in health facility as allotted under Punjab Health Systems Corporation, Punjab from 01.02.2018 to 30.04.2018.

During the dissertation the student's performance was satisfactory.

We wish him success in all his future endeavors.

(Varun Roojam) I.A.S.
Managing Director
Punjab Health Systems Corporation
-Cum-Secretary Health and Family Welfare, Pb.

Certificate of original work

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled "Assessment of quality testing and drug approval process before dispatch for medicines under supply chain system of Punjab Health System Corporation" and submitted by Prashant Vaishnav Enrollment No 0075 under the supervision of Prof. Rahul Sharma for award of MBA in Pharmaceutical Management of the University carried out during the period from 1st February 2018 to 30th April 2018 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

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Acknowledgement

I would like to express my deep sense of gratitude for my mentor and Intern coordinator "Mr. Rahul Sharma Professor, IIHMR University, Jaipur, Rajasthan. I am greatly indebted to him for providing their guidance at all stages of the study, his constructive suggestions and continuous encouragement helped me to complete this project."

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Prashant Vaishnav

IIHMR University

Background:

Quality assurance is a wide concept that covers all aspects that collectively or individually impact the quality of the product. That is, the sums of organized arrangements that are made with the aim of ensuring pharmaceutical products are of the required quality as per the intended use (RS Calibration, 2016).

Quality assurance (QA), as defined by GLP, is a team of persons (often called the Quality assurance unit – QAU) charged with assuring management that GLP compliance has been attained within the laboratory. QA must be independent from scientists involved in the operational aspects of the study being performed. QA functions as a witness to the whole non-clinical research process.

A Quality based approach helps in identifying the gaps in service delivery and tracing its roots and linking them to organizational processes. It builds a system of taking effective actions for traversing the gaps, periodic assessment and improving the quality. Quality Assurance Guidelines have been developed by the Ministry of Health & Family Welfare for addressing the concerns of public.

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

"Quality management in the drug industry: philosophy and essential elements" outlines the general concepts of quality assurance as well as the principal components or subsystems of GMP, which are joint responsibilities of top management and of production and quality control management. These include hygiene, validation, self-inspection, personnel, premises, equipment, materials and documentation.

"Good practices in production" (section 16) (WHO, 2005-2006) and "Good practices in quality control" (section 17) (WHO, 2005-2006), provide guidance on actions to be taken separately by production and by quality control personnel for the implementation of the general principles of quality assurance.

GMP is an important part of a comprehensive system of quality assurance. They also represent the technical standard upon which is based the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. The first GMP text

published by WHO was developed during 1967–69 upon request by WHO's Member States and was revised in 1975.

In the drug industry at large, quality management is usually defined as the aspect of management function that determines and implements the "quality policy", i.e. the overall intention and direction of an organization regarding quality, as formally expressed and authorized by top management. The basic elements of quality management are:

1. an appropriate infrastructure or quality system, encompassing the organizational structure, procedures, processes and resources.
2. Systematic actions necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality. The totality of these actions is termed quality assurance.

Quality control is the part of GMP concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product (WHO, 2005-2006).

Review of literature

In-Process Quality Assurance is responsible for affixing hold labels to the damaged packs, ensuring the recording of temperature, to identify the documentation errors wherever found out, identification of approved vendors and new vendors, ensuring the status of the materials, i.e., quarantine, approved and rejected, ensuring that the materials stored in appropriate storage areas (Veena G, 2015).

Quality assurance giving line clearance for the dispensing of batches and verification of weighing balances calibration and cross contamination of the materials can be prevented by the role of QA. It is concluded that the QA plays a prominent role in every activity in warehouse and ensures that the results produced meets the GMP specifications (Veena G, 2015).

The quality in the pharmaceutical industry has become a very important topic. Since the world has gathered together to harmonize its practices and guides and the launching of the FDA current good manufacturing practices – the cGMP; for the 21st century – there has been a growing awareness for the significance of the quality of the pharmaceutical products.

Quality assurance is a good practice in the manufacture of pharmaceutical products, as it is the process of vouching for integrity of products to meet the standard for the proposed use. It is an obligation that ensures manufacturers meet the needs of end-user needs in terms of safety, quality, efficacy, strength, reliability, and durability. Quality is a benchmark of perfection for the end-user (RS Calibration, 2016).

The practice of quality assurance focuses on planning, documenting and agreeing on a set of guidelines that are crucial for assuring quality. It is a managerial tool and is process-oriented. Usually, planning for quality assurance is undertaken at the beginning of any project. (dialog information Tech.)

Objectives:

- To assess the current situation of quality testing process under supply chain system of Punjab Health System Corporation.

- To analyze the time taken by drugs in quarantine area of drug warehouse.

- To determine how many sample of drugs were tested as per standard day's guidelines.

- To analyze the possible gaps in supply chain system of PHSC for the delays in pre-dispatch testing of items.

Research Methodology:

Study Type: Descriptive study

Duration of study: from 1st Feb 2018 to 30th April 2018 (3 months)

Type of Data: Secondary Data

Location: Punjab health service cooperation, Mohali (Punjab)

Collection of Data: for secondary data Articles and journals, e-Aushadhi system, and Quality control cell Kharar Warehouse.

Introduction:

A Quality based approach helps in identifying the gaps in service delivery and tracing its roots and linking them to organizational processes. It builds a system of taking effective actions for traversing the gaps, periodic assessment and improving the quality. Quality Assurance Guidelines have been developed by the Ministry of Health & Family Welfare for addressing the concerns of public.

The quality assurance in supply chain management of pharmaceutical is to make certain each medicine reaching to patients with effective, safe, and standard quality and provided at the time requirement.

After procuring the drug from supplier, supplier supplies the ordered items in the warehouse in given time period. After that drug sample sent for quality testing in laboratory. After medicine passed by quality testing then Stock become active and it is ready for issue.

Guideline provided some standards for medicine in quarantine area. That means how much time consumed by drugs in quarantine area. According to the standard guideline, quality testing days for sterile items are 21 days and 10 days for sterile items . It means the items quality should be tested within given time.

Quarantine Area

It is area when new stock received from suppliers in the warehouse. And then send the sample of new stock for quality testing in laboratory.

During the quality testing till the sample result is not declares, for that time period new stock kept in quarantine area. After items status got passed then it will be showing active stock. If sample got failed it will be show is inactive stock. Then stock is replaced by the firm and then government takes any action against the firm according to their policy.

Characteristics to determine the quality of medicine:

- Availability of correct Active Ingredient at correct amount.
- Medicine is not contaminated with harmful substances
- Consistency in shape, size and dosage form
- Pharmacopeia Standard, for good quality medicine characteristics should be match to the pharmacopeia standards.

- Bioavailability refers to the speed and completeness with which an administered medicine enters the blood stream. It must be consistent to provide a predictable therapeutic result.

E-Aushadhi

e-Aushadhi, which deals with the management of stock of various drugs, sutures and surgical items required by different district drug warehouses. The main aim of 'e-Aushadhi' is to ascertain the needs of various district drug warehouses such that all the required materials/drugs are constantly available to be supplied to the user district drug warehouses without delay. This includes classification/categorization of items, codification of items, quality check of these items, etc and finally issuing drugs to the patients, who is the final consumer in the chain.

Benefits of e-Aushadhi:-

- It Brings Transparency in the Process of Drug Inventory Management and Distribution.
- Provision to maintenance of Expiry date for an item Shelf life for an item wherever applicable.
- Supplier Interface for viewing PO, entering Challan.
- Customizable Alert Management.
- Stock Ledger, Drill-Down Reports.
- Lab Interface for entering the QC Reports.

Pre dispatch testing

It is a necessary activity in which latest received stock in warehouse, and drug inspector select random sample and then send for the quality testing in Quality control laboratory before distribution of items.

This procedure deals with both quality assurance and quality checking of drug. During the analysis is going on all the stock kept in quarantine area.

Packaging

- The packing in each carton shall be strictly as per the specification mentioned.
- The label in the case of Injectable should be clearly indicated whether the preparation is meant for IV, IM, SC etc.
- Small tablets packed in blister should be so packed to facilitate removal of tablets without breaking or crushing
- The medicine store between 2 to 8 degree centigrade (cold and cool storage) shall have to supply in appropriate transport condition using cold chain supply.
- The generic name of the drug should be printed in clearly legible bold letters.
- All packaging must be proper sealed.
- All containers like bottle, tins, carton, tubes etc must be secure with pilfer proof seals to ensure genuineness of the product packed and the correctness of the contents.

Analysis time period as per Guideline

Particulars of item	Testing period & submission of report
i. Tablets, capsules, pessaries, Ointments, Power and Liquid Oral Preparation (non-sterile product)	Within 10 days from the receipt of sample.
ii. I.V. Fluids and Injectables and other items requiring test for sterility. (Sterile product)	Within 21 days from the receipt of the sample

According to the standard days for non sterile item is 10 days and for sterile item is 21 days that means quality testing result of item should be declare in given standard days. If they cross the standard day's penalty will be applied automatically.

Penalty in case delay in test reports-

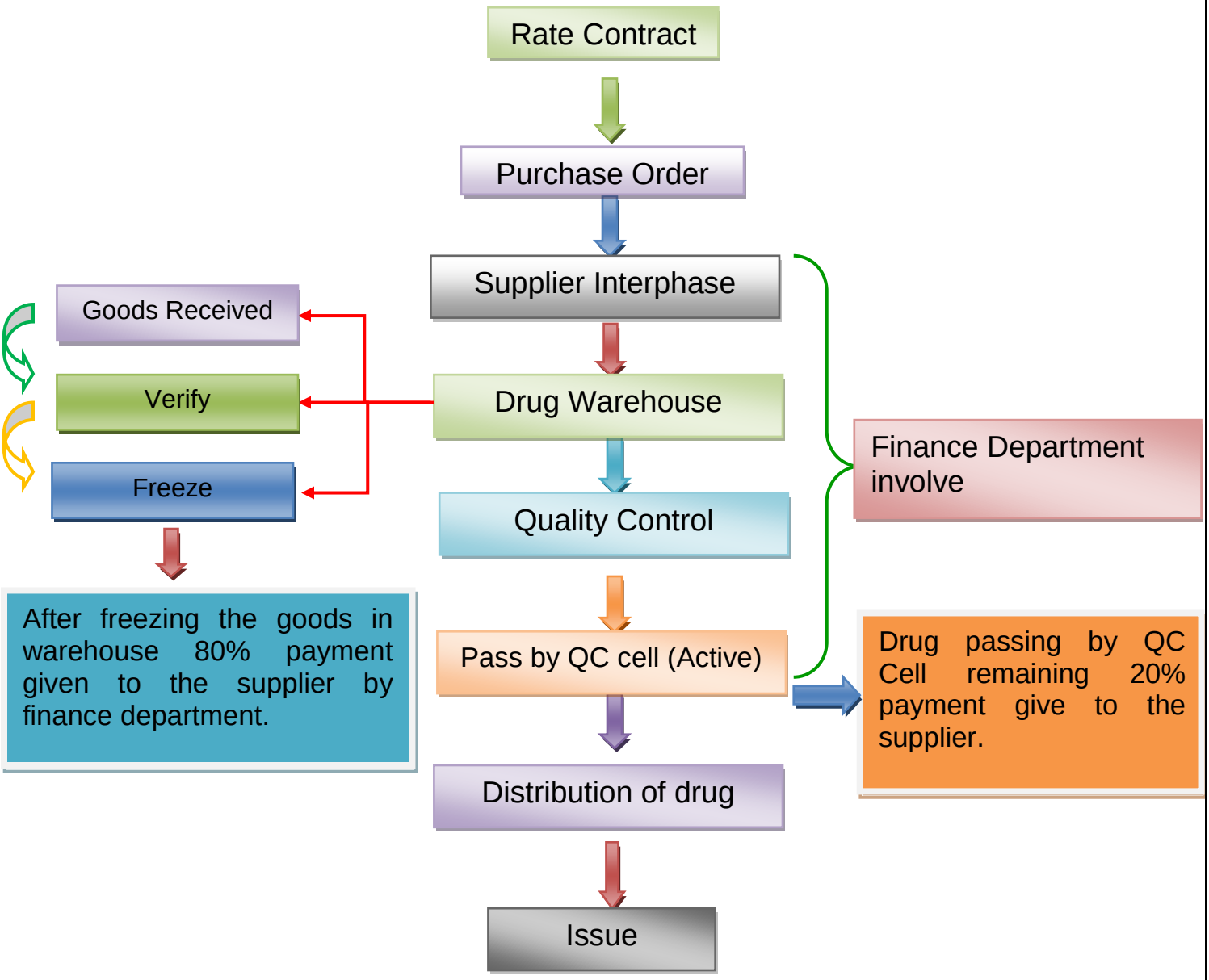
a) Delay up to one fourth period of the testing period: - 2.5% penalty.
b) Delay exceeding one fourth but not exceeding half of the prescribed testing period: - 5% penalty.
c) Delay exceeding half but not exceeding three fourth of the prescribed testing period:- 7.5% penalty.
d) Delay exceeding three fourth of the prescribed testing period: - 10% penalty will be applied.

Label of Punjab Health System Corporation

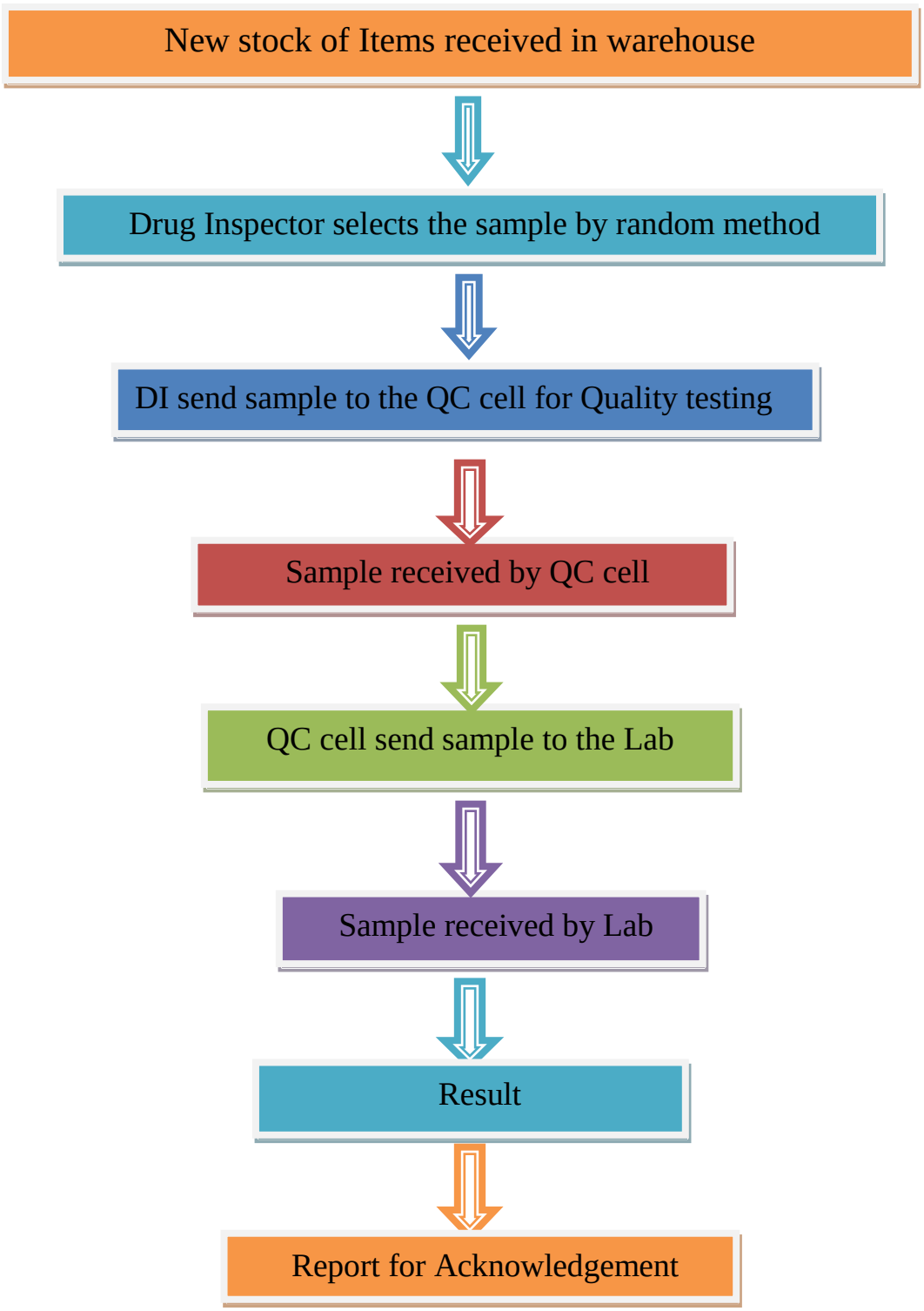
- All box should be carry a large outer label clearly indicate that the product is for "Govt. of Punjab Supply Not to be sold" with logo of Punjab health system corporation.
- The label on the carton should be large and clear.
- It should carry the correct information about the product.
- The name of the drug product.
- A list of the active ingredients (if applicable, with the INNs), showing the amount of each present and a statement of the net contents (e.g. number of dosage units, weight, volume).
- The batch number assigned by the manufacturer.
- The expiry date in an uncoded form.
- Any special storage conditions or handling precautions that may be necessary.
- Directions for use, and warnings and precautions that may be necessary.
- The name and address of the manufacturer or the company or the person responsible for placing the product on the market.

Outline of procurement of drug to issue of drug/ medicine

At the time of medicine procurement, the supplier should be meet their terms and condition according to the tender policy. They should select that supplier who gives medicine in lower rate. Medicine select on based on safety, efficacy, effectiveness and proper dosage form with the longest shelf life. After that generate purchase order from the e-Aushadhi Software. Supplier can easily understand how much order they need to supply in warehouse. (fig.1)



Sample Testing Procedure

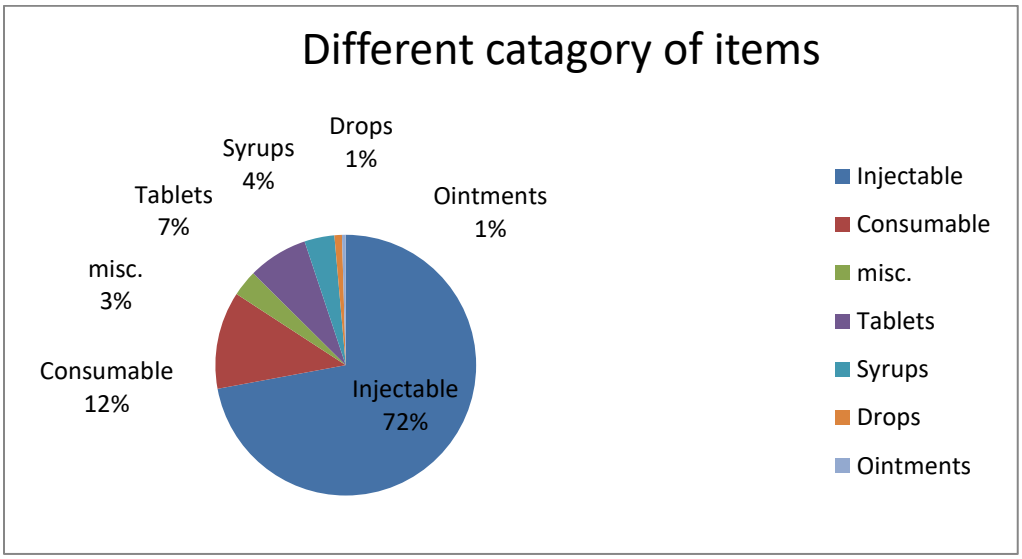


Analysis

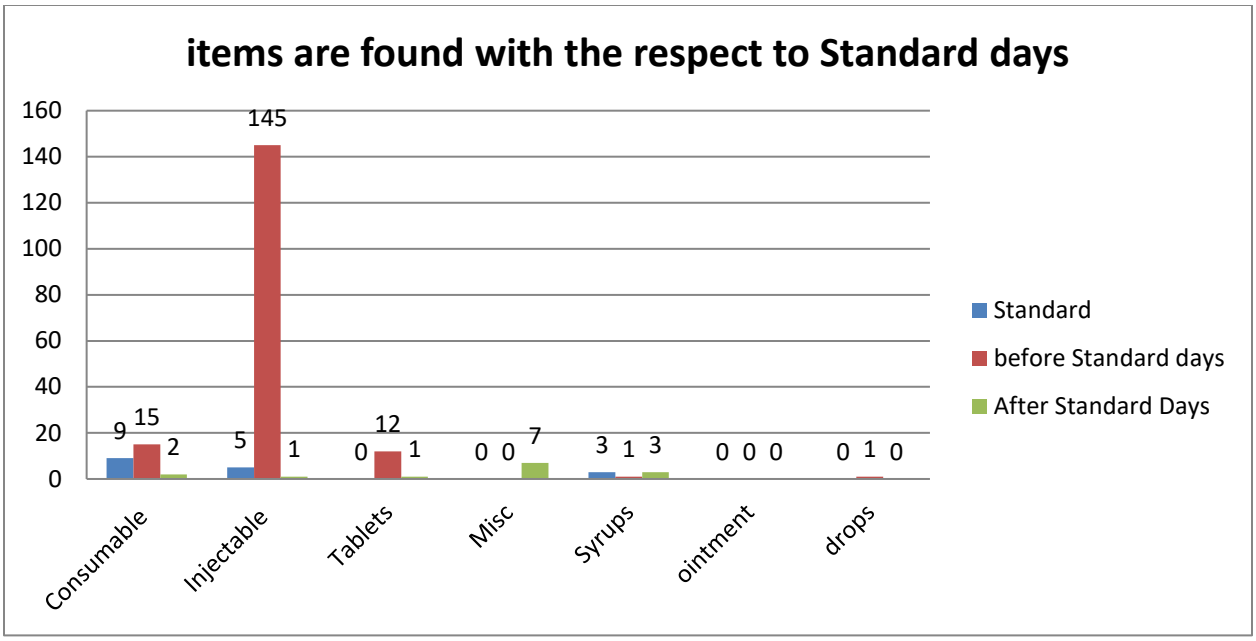
Data was collected of 4 month (Nov-2017 to Feb- 2018) from warehouse Kharar. In this four month total 215 items were received in Quarantine area at warehouse and after receiving all items, Drug inspector select sample by random method and then send it for the Quality testing.

Out of 215 items

1. Injectable are 155
2. Consumables are 26
3. Tablets 16
4. Syrups are 8
5. Miscellaneous are 7
6. Drops are 2
7. Ointment is 1



The Graph Showing that most part of items are Injectable 72%, consumables are 12%, Miscellaneous are 3%, Tablets are 7%, Syrups are 4%, Ointments are 1% and last one Ear/Nasal Drops are 1%.



Consumable

The Standard days for consumables (sterile) items are 21 days period of quality testing in laboratory.

- 9 items were found as per standard time 21 days (that means they prove their quality according to standard days).
- 15 items were found before standard days (this much no. of items took less time to prove their quality).
- 2 items were found above standard days (this much no. of items took more time to prove their quality).

Injectable

The Standard days for Injectable (sterile) items are 21 days to quality testing in laboratory.

- 5 items were found as per standard time 21 days (that means they prove their quality according to standard days).
- 145 items were found before standard days (this much no. of items took less time to prove their quality).
- 1 item is found above standard days (this much no. of items took more time to prove their quality).

Tablet

The Standard days for Tablets (non sterile) items are 10 days to quality testing in laboratory.

- 0 items were found as per standard time 10 days (that means they prove their quality according to standard days).
- 12 items were found before standard days (this much no. of items took less time to prove their quality).
- 1 items were found above standard days this much no. of items took more time to prove their quality).

Miscellaneous

The Standard days for Miscellaneous (non-sterile) items are 10 days to quality testing in laboratory

- 0 items were found as per standard time 10 days.
- 0 items were found before standard.
- 7 items were found above standard days (this much no. of items took more time to prove their quality).

Syrups

The Standard days for Syrup (non-sterile) items are 10 days to quality testing in laboratory.

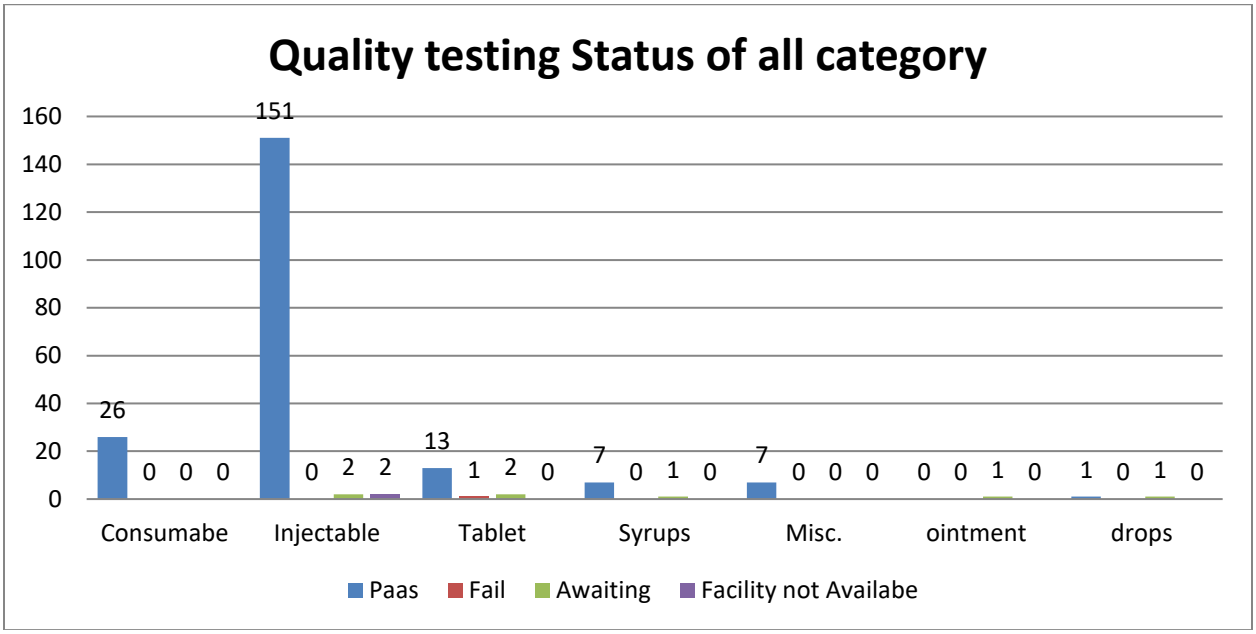
- 3 items were found as per standard time 10 days (that means they prove their quality according to standard days).
- 1 item is found before standard days (this much no. of items took less time to prove their quality).
- 3 items were found above standard days (this much no. of items took more time to prove their quality).

Ointment

- No items were found in any of standard category, because only one item is found in this category, which result is in waiting.

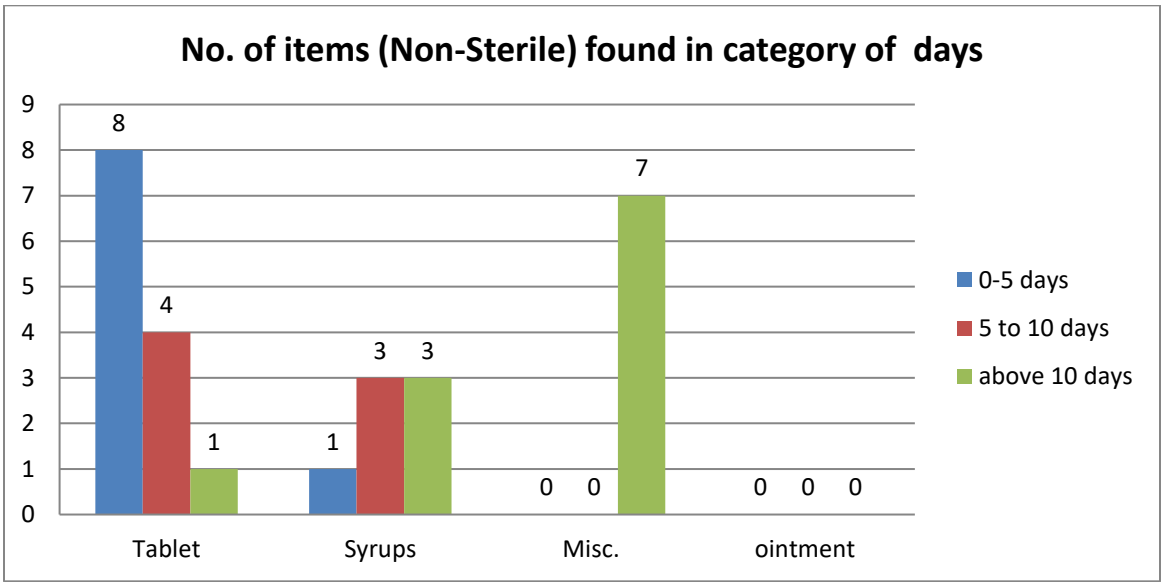
Drops

- In drops category only two items were found. In which one item is found in before standard days. And second one is waiting for the result.

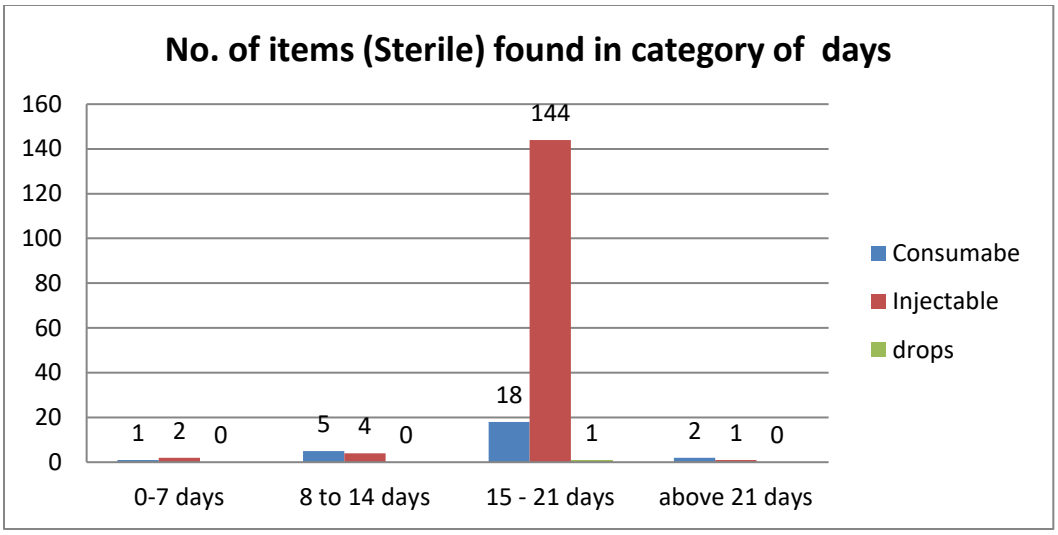


- Total consumable items are 26. In which all items got passed form quality testing. None of item got failed.
- Total Injectable items are 155. Out of 155 items, 151 items got passed form quality testing. None of item has been substandard, 2 items are waiting for result and for 2 items facility not available.
- Total Tablet and capsule items are 16. Out of 16 items, 13 items got passed form quality testing. 1 item has been substandard and 2 items are waiting for result.
- Total Syrups items are 8. Out of 8 items, 7 items got passed form quality testing. None of item has been substandard, 1 item is waiting for result.
- Total Syrups items are 7 and all items got passed by quality testing procedure. None of item has been declared substandard.
- According to the data in Ointment category only one item is received and that item result not declares yet, result is awaiting.

- In Ear/Nasal drop category only two items are received in warehouse. In which 1 item got passed by quality testing and it took minimum days (before standard days) to prove their quality as per Indian pharmacopeia. And one item result is waiting.



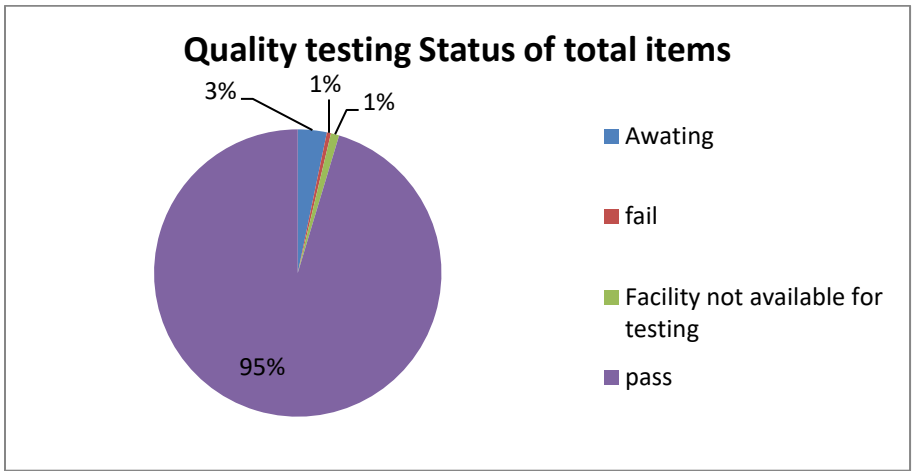
- According to the data most of the tablet items were found within 10 days as per standard of Tablets (non sterile) item. In days of category 0-5 highest no. of items are found, in 5-10 days of category we found 4 Tablet items. But 1 Tablet item is found above standard days.
- Most of the Syrup items are found within 10 days as per standard of Syrups (non sterile) item. In days of category 0-5 only 1 item is found, in 5-10 days of category found 3 items. But 3 items is found above standard days (this item took more time to prove their quality).
- In Miscellaneous category all items were found in above standard days (after 10 days). That means this items are not as per standard days.
- Ointments of items were not found in any days of category. Because only one item is available in ointment category and result is awaiting.



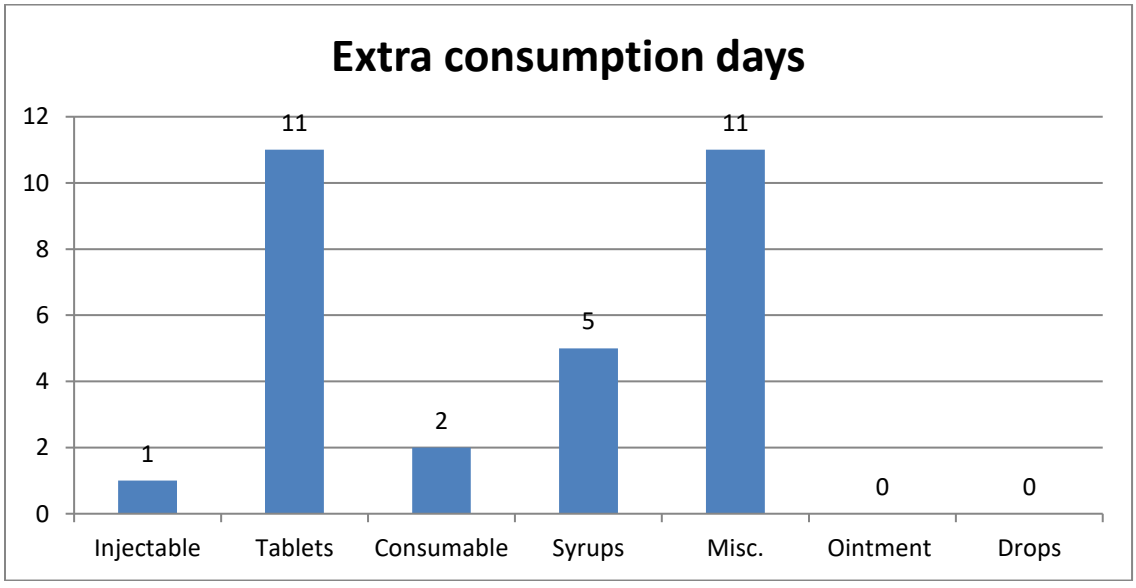
- According to the data most of the items of the Consumables were found within 21 days as per standard of consumables item. In days of category 0-7 one item is found. In days of category 15-21 highest no. of items are found. But 2 items are found above 21 days (above standard days).
- Total 155 numbers of items were found in injectable category. According to the data most of the items are found within 21 days as per standard of Injectable item. In days of category 0-7 only 2 items are found, in 8-14 days of category we found 4 items. In 15-21 days category we found highest no. of items that was 144. But 1 item is found above 21 days (above standard days).
- In drops category only 2 items were found. In which one item is found in days of category 15-21. And other one is waiting for result.

Conclusion

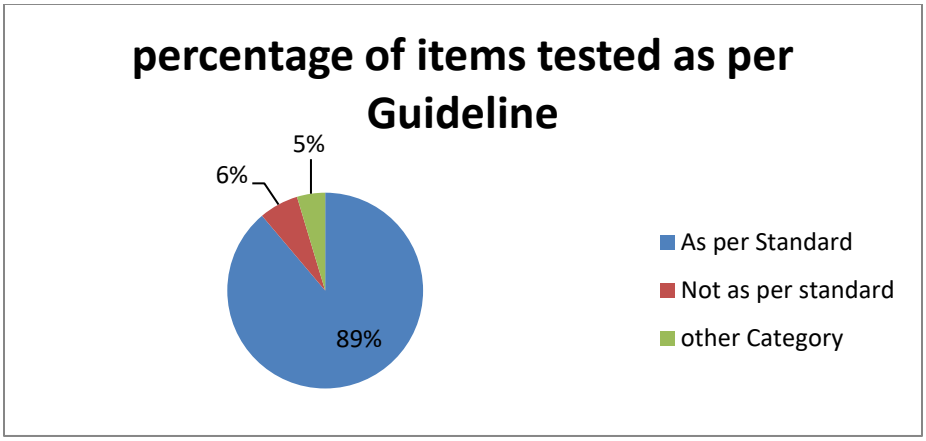
- After analyzing the data, it found that the current situation of the quality testing process of item as follows-



- Based on analysis it found that, total 215 numbers of items sent for the Quality testing process. In which 95% items has been passed by the quality testing process, it become active stock so that this items got approval for distribution of drug/medicine in hospitals and retail shops. 1% of item got substandard (failed) because their condition are not met as per guideline (Indian Pharmacopeia), for 1% of items testing facility is not available (like- Anti Rabies inj.) and 3% of items are still waiting for their result.



- According to the analysis of data, it found that the Injectable items and Consumable items are consuming minimum extra time after Standard days. Syrup items are consuming extra 5 day after finishing their standard days but Tablets and miscellaneous items are consuming maximum time (11 days extra) after finishing their Standard days And Ointment or Ear/Nasal Drops items are not consuming extra days. Because in case of ointment category only one item is found and which result is not declare yet, because its quality testing process in going on. And in case of Ear/Nasal Drops only two items were found in which one item has been passed by quality testing procedure (before the standard days). But one item quality testing procedure is going on (result not declare yet).



- In the above analyzed data conclude that 215 items sample sent for the quality testing. In which 89% of drug sample tested as per the guideline (in respect to their standard consumption period). 6% of drug sample tested not as per guideline (this item took more consumption days in respect to their standard consumption period). And the other 5% of category includes substandard item, item which result is waiting and also added that item which facility not available for quality testing.
- By the analysis it concludes that the 6% of items quality testing process has been delayed, this is the gap occur in pre-dispatch quality testing. This delay in quality testing process can cause problem in distribution of medicine at right time to right patient.
- Quality Assurance is focus on a set of guideline, so according to the data 89% of items are tested as per standard guideline that's why we can say this much percentage of items agreeing on quality assurance as per standard guideline that means this are the quality product.

Recommendation

- A gap has been found in pre-dispatch testing of items. The gap is like that, some items consuming more days in respect to standard days. So that's why they need to fill the gap through improving their quality testing procedure so they can test items in the given standard period.
- The day when result of the sample declares, at the same day report of sample should be sent to quality control department for the acknowledgement, whether the sample got passed or substandard.
- Sample should be send to quality testing at same day after receiving the new stock in the warehouse.
- Assessment of the quality of items and related to time required approval of drug/item it should be helpful for the system/
- Item/Product quality testing should be finish as per the standard guideline.

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