Summer Training at
Gujarat Medical Service Corporation Ltd., Gujarat
(April 3 to June 2, 2017)

Quality Analysis of List of Quarantine Drugs and the Gaps in the Approval of Drugs at Gujarat Medical Service Corporation Ltd., Gujarat

By
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MBA Pharmaceutical Management
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INSTITUTE OF HEALTH
MANAGEMENT RESEARCH
(WHO Collaborating Centre for District Health System Based on Primary Health Care)

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that **Mr. Gaurav has** undergone summer training in **Gujarat Medical Service Corporation Limited at Gandhinagar** from **3rd April to 2nd June, 2017**.

The candidate himself completed the project assign to him during summer training. His approach to the project was sincere and proactive. This summer training is in partial fulfillment of the course requirement recommended for the award of MBA in Pharmaceutical Management

I wish him success in all his future endeavors.

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The certificate is awarded to

Gaurav

In recognition of having successfully completed his

Summer training in the department of

Logistics & Supply chain

and has successfully completed his Project on

Quality analysis of list of quarantine drug and the gap in the approval of drugs

3rd April, 2017 – 2nd June, 2017

At

Gujarat Medical Services Corporation Limited

We wish him all the best for future endeavors

GUJARAT MEDICAL SERVICES CORPORATION LTD. GMSC GANDHINAGAR

26/6/17

Managing Director , GMSCL

ACKNOWLEDGEMENT

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GAURAV

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INTRODUCTION

About the organization

The Central Medical Stores Organization (C.M.S.O) was established in 1978 under Health and Family Welfare Department. Govt. of Gujarat and was entrusted with the functions of procurement, storage, distribution of medicines surgical goods medical equipment / instrument and insecticides for the health care institutions under Govt. of Gujarat.

With the changes in the healthcare arena there was a felt need of developing new as well as upgrading the existing functioning and processes of CMSO, With the view to match the changing demands and pace of development in the sector, CMSO was transformed into "Gujarat Medical Services Corporation Limited" (GMSCL) as an autonomous body and was incorporated under companies act, for systematic procurement, inventory management, Management information.

Functional Areas:

The Main Functions of GMSCL are as following:

- Procurement of essential, lifesaving quality medicines, surgical goods & Insecticides, and their timely availability by creating highly decentralized storage capacity & distribution network.
- Procurement of quality medical equipment/Instrument and its maintenance for entire product life cycle.
- Establishment of Diagnostic Medical Service Center foe early diagnosis & ease of treatment for beneficiaries.

Background

This protocol offers guidelines for conducting quality assessment and strengthening of qualitative product, as part of a broader process of quality assurance of a qualitative product to develop guidelines that are applicable to qualitative product conducted within the state health context, and potentially beyond. The process of testing is performed to assess, maintain, and assure the continuum of quality of goods while receiving, transporting or supply.

Need for the study:

- The assessment of goods is performed against the standards defined. The time between the goods received at the warehouse and their supply to the institution takes much time due to which the supplies received are delayed or are not at the prefixed time. The need to conduct an analysis for the drugs received and taken from the receival to the supply could help us to identify the gaps, and take measures to curb the time wasted. The present quality check mechanism has been studied to understand the operation management as well as could also be useful to a performance measurement system for warehouse activities to developed in alternative ways.

TITLE: Qualitative analysis of list of quarantine drugs and gaps behind delay of their approval.

OBJECTIVE: To identify the gaps occurring within the organization regarding approval of drugs under Pre-Dispatch Testing (PDT), quarantine drugs.

Sub objective:

- To know how many drugs are tested as per the standard guidelines.
- The time consumption of drugs in quarantine area. (by comparing with the Standards set by the organization)

Research Methodology

Study	descriptive
Data collection	secondary data
Sampling technique	purposive

WHO GUIDELINES

1.INTRODUCTION AND GENERAL CONSIDERATION

WHO expert committee on specifications for pharmaceutical preparation expressed the opinion that a comprehensive review of the quality assurance in pharmaceutical supply system might be of value for national programs in the regulatory control of drugs and suggested that a suitable document should be prepared

Process & Operation

QUALITY ASSURANCE OF DRUGS

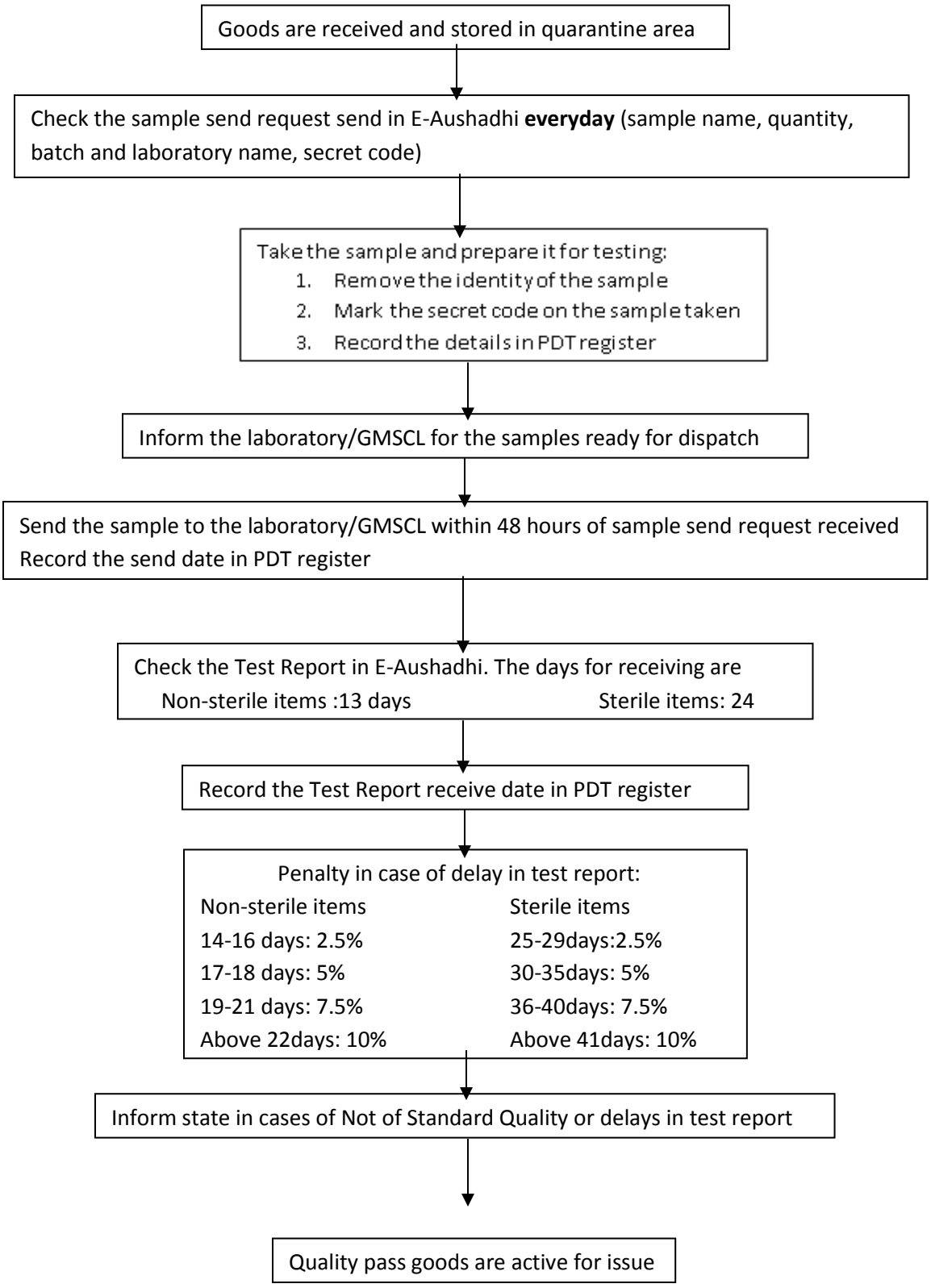
GMSCL assures quality of drugs supply to all Health Institutions of Gujarat Government. This is assured by pre-dispatch testing and testing as per Drugs and cosmetics Act 1940 & rules there under. Thus, GMSCL keeps watch on the quality Drugs supply to the Government Health Institutions.

STANDARD OPERATING PROCEDURE (SOP)

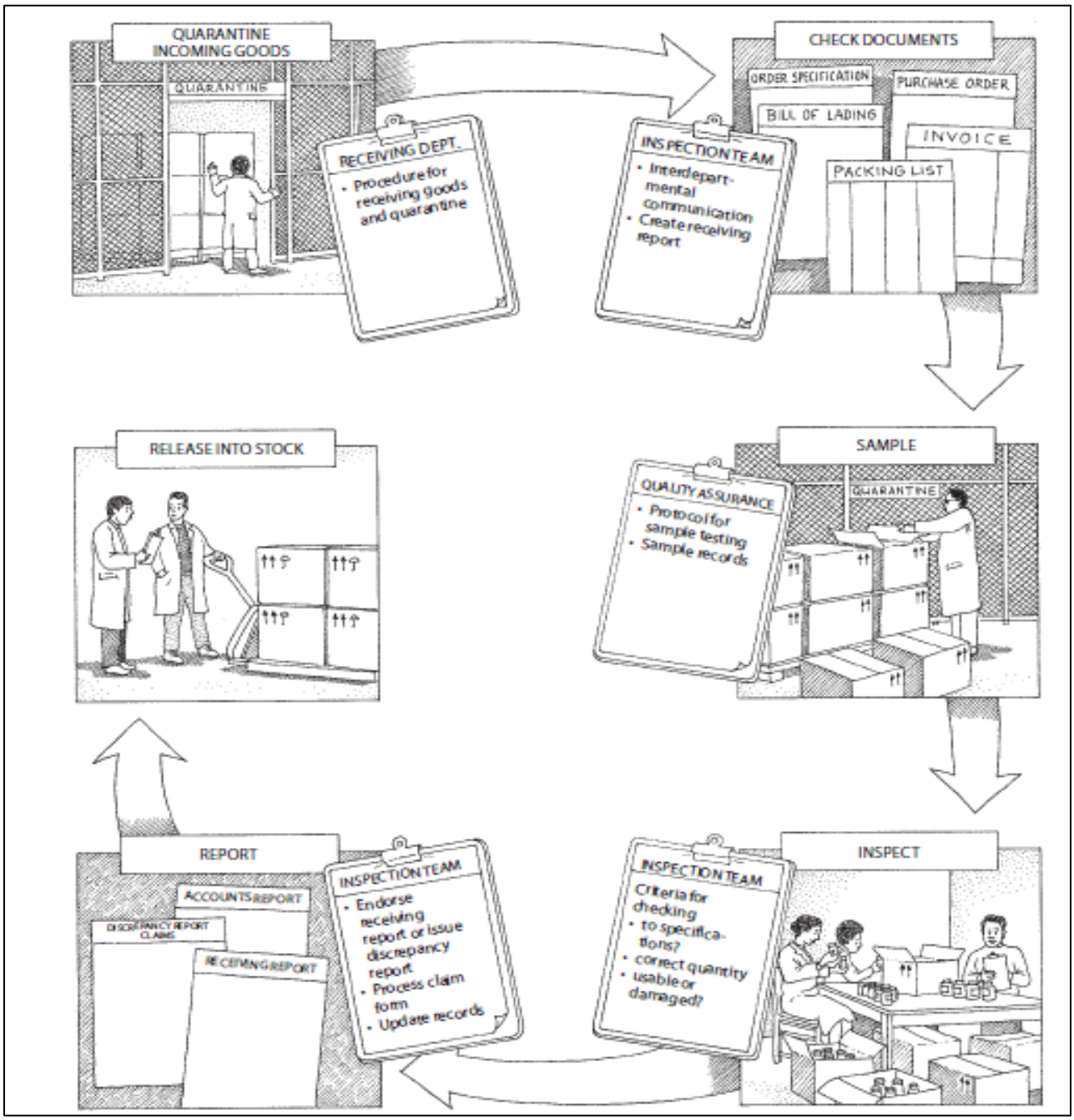
QUALITY ASSURANCE (QA)

- Drugs are to be received at Regional Ware house along with the test reports of NABL / Government approved public testing laboratories.
- Regional Ware house personnel acknowledge the receipt of drugs as per the Rate contract & purchase order.
- All the receipts are kept in quarantine.
- Quality Assurance personnel of Regional Ware house encode the sample and send it to empanel laboratory / Baroda Drug laboratory as per the Head Quarter request.
- All the results are received at Head Quarter.
- Head Quarter acknowledges receipt of Test reports and releases the drugs which having Standard Quality report.
- Drugs which are not of standard quality are returned to the manufacturer.
- The supply of vaccines and serums can be distributed to the hospitals as per the clearance test report of Central Research institute given by manufacturer.
- Cross verification of Quality of drug from more than one laboratory.

Activity layout



Pathway of the process of the drugs from quarantine area to the stock released area



QUALITY CHECKING (QC)

- Samples are drawn from all Regional Ware house as well as health institutes as per D & C Act 1940 and rules thereunder by notified Drug inspector of GMSCL / FDCA
- If it is declared that sample is not of standard quality, then immediately Head Quarter inactivate online stock.
- Regional Ware house and Direct Demanding Officers are being informed about NSQ Drug by circular also.
- Replacement / Recovery notice to be issued to manufacturer for total quantity of supply.
- Firm is to be debarred as per the debarment policy of GMSCL.
- In case of complaint from any government institute, immediate action to draw the sample is taken and testing is to be carried out on priority basis.

PRE-DISPATCHED TEST (PDT)

i. It is the activity which deals with the quality assurance and quality checking of drugs in the logistic and supply management. It is essential step of procurement and supply of the drugs.
ii. This include laboratory testing of received stock of medicines from supply before delivery.
iii. Till the laboratory analysis is going on the proper stock is kept in a quarantine area and they should not be supply.

Definition

- **Good Manufacturing Practices (GMP)—**Performance standards that WHO and many national governments established for pharmaceutical manufacturers covering, for example, personnel, facilities, packaging, and quality control.
    a) GMPs are part of the quality assurance activities that ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and required by the drug regulatory authorities

- **Quarantine area: -** The items which were received by the supplier are kept in the quarantine area for laboratory approval.

I. If the laboratory test passes the items is active and ready for issue.
II. It the laboratory test fails the items were returned to the vendor.

The mechanism of quality testing at warehouse for received health commodities
Sample: -

Sample Testing: The Senior Drug Inspector of the Corporation shall collect Sample of the material, and will be sent for testing to an approved laboratory. In all supplies 1% of the supply value & service charge, education cess (as applicable)

a) **Pre-dispatch Testing of Samples:**

1) The samples of stores to be supplied against this rate contract will be drawn by an authorized person so nominated by the Managing Director, G.M.S.C.L., and tested at a laboratory approved and licensed by the Commissioner.
2) If the goods are declared as standard, it is acceptable provided that the R.C. holder must supply the drugs and other items of stores having 100% or more (up to upper Pharmacopoeia limit) potency irrespective of lower Pharmacopoeia limit. This will be treated as the criteria at the time of acceptance / replacement of drug.
3) Once accepted (or replaced) the stores must confirm to the usual Pharmacopoeia limits of potency, if tested at any time during its shelf life till its expiry date the potency of the drug.

Visual inspection

PACKAGING OF DRUGS:

- The labels in the case of injectable should clearly indicate whether the preparations are meant for IV, IM, SC, etc.
- Small tablets packed in blisters should be so packed to facilitate removal of tablets without breaking or crushing.
- The medicines store between 2 to 8 degrees (cold and cool storage) Centigrade shall have to supply in appropriate storage/ transport condition using cold chain supply.
- The Generic name of the drug should be printed in clearly legible bold letters.
- **All containers** i.e. bottle, tins, cartons, tubes etc. must be secured with pilfer proofs seals to ensure genuineness of the products packed and the correctness of the contents. “A" type plastic container.

LABEL:

a) Every corrugated box should carry a large outer label clearly indicating that the product is for "Govt of Gujarat Supply-Not for Sale" with Logogram of GMSCL.

Time for the sample report

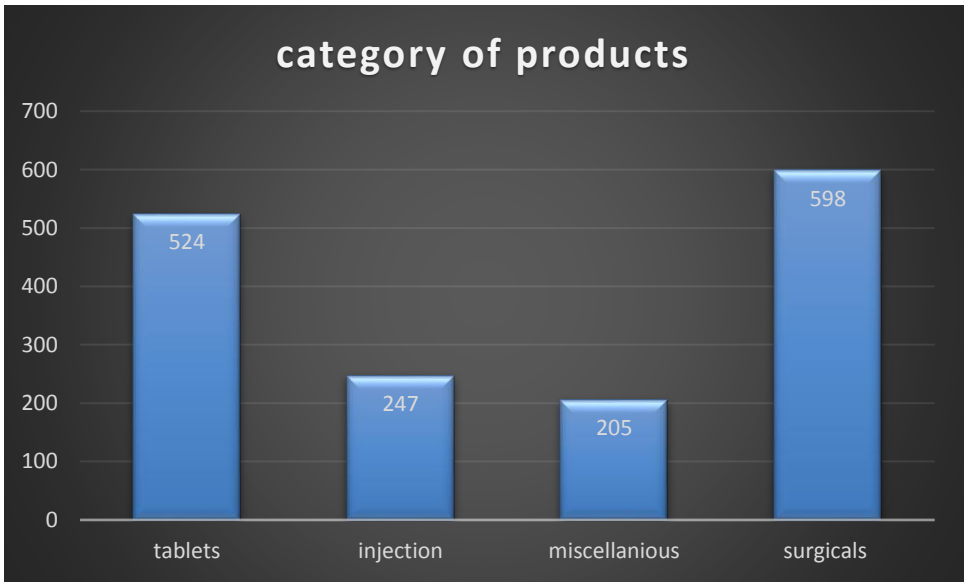
Penalty in case of delay in test report:

Non-sterile items	Sterile items
14-16 days: 2.5%	**25-29days:2.5%**
17-18 days: 5%	**30-35days: 5%**
19-21 days: 7.5%	**36-40days: 7.5%**
Above 22days: 10%	**Above 41days: 10%**

Data analysis and interpretation

Total product: - 1574

Category	No. of items
Tablets	524
Injections	247
Miscellaneous	205
Surgical	598

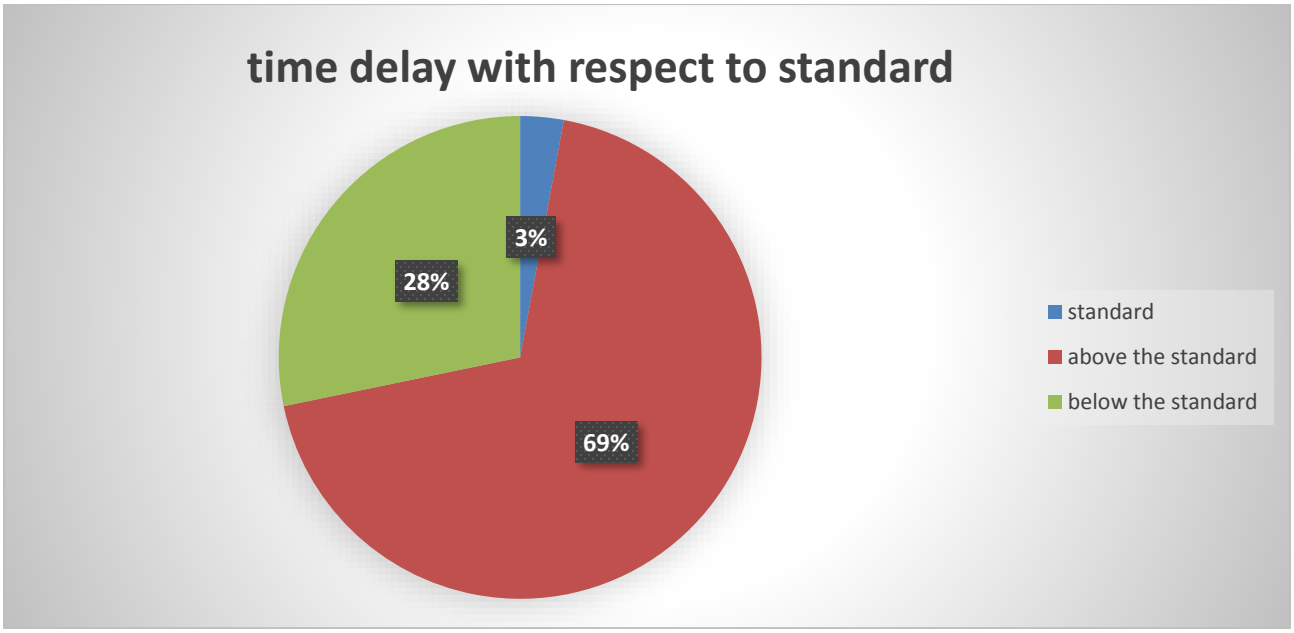


Interpretation: - the total no. of drug product is 1574 we have divided in four categories

1) Tablet and capsule (524)
2) Injections (247)
3) Miscellaneous (205)
4) Surgical (598)

Tablets section

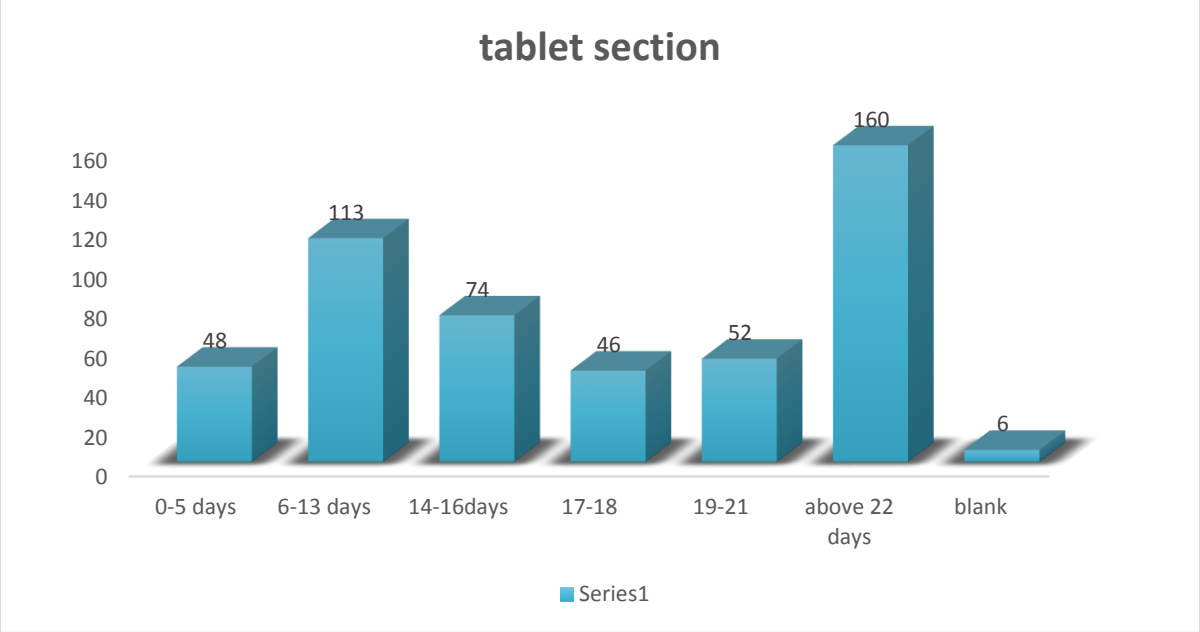
Category	No of drugs found
Standard (13 days)	15
Above the standard (after 13 days)	356
Below the standard (before 13days)	146



Interpretation: - the standard time for the tablet section is 13 days when the sample is sent from the warehouse.

1. 3% drugs are found as per the standard time (as per standard)
2. 69% of drugs found above the standard (they took more than 13 days)
3. 28% drugs found below the standard (they are taking less than 13 days to produce result).

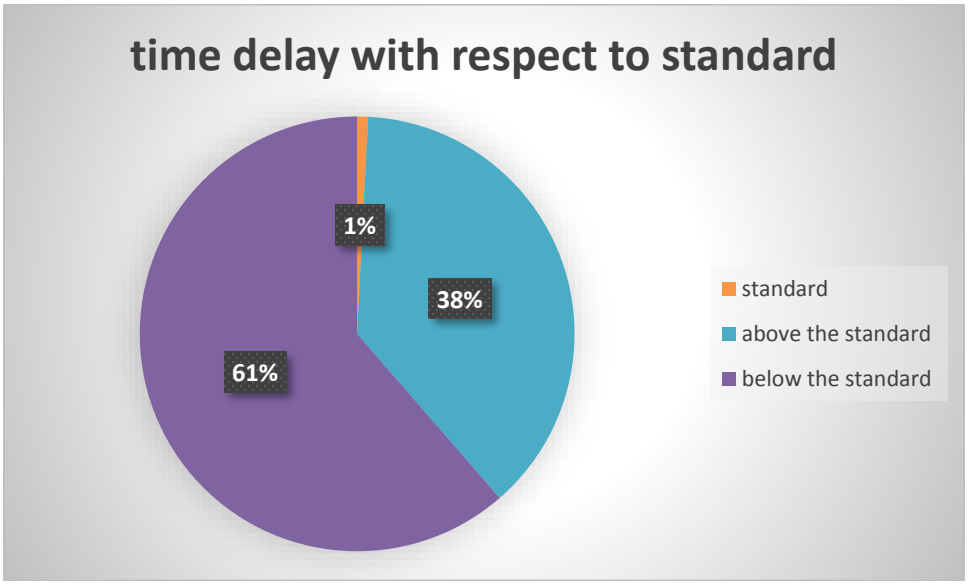
No. of days	No. of drugs found
0-5 days	48
6-13 days	113
14-16days	74
17-18	46
19-21	52
above 22 days	160
blank	6



Inference: - the data is combined as in group of days as we know that the non-sterile product takes 13 days but some are the drugs which take more than 13 days and the no. of drugs which take more than 13 days are more as compared to other group of days.

Injections

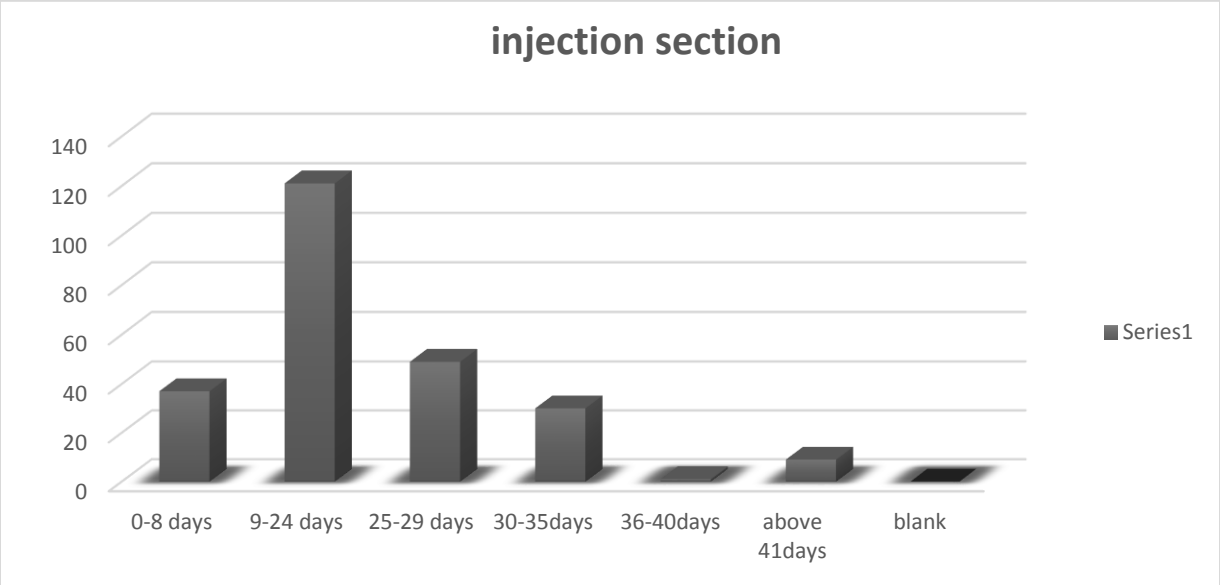
category	No. of drugs found
Standard (24days)	2
Above the standard (after 24days)	93
Below the standard (before 24days)	151



Interpretation: - The standard time for the injectables section is 24 days when the sample is sent from the warehouse.

1. As only 1% drugs are found as per standard (that means report received as per time)
2. 38% of drugs were found above the standard (they take time for testing) and
3. 61% drugs below the standard (their report received before 24 days.

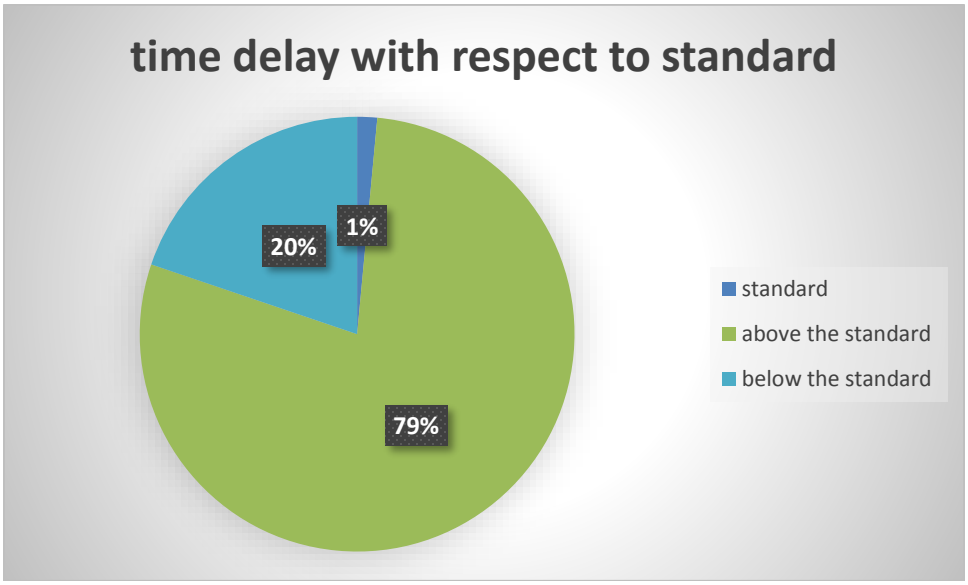
No. of days	No. of drugs found
0-8 days	37
9-24 days	121
25-29 days	49
30-35days	30
36-40days	1
above 41days	9
blank	0



Inference: - the data is combined as in group of days as we know that the sterile product takes 24 days but some are the drugs which take more than 24 days and the no. of drugs which take less than 24 days are more as compared to other group of days.

Miscellaneous

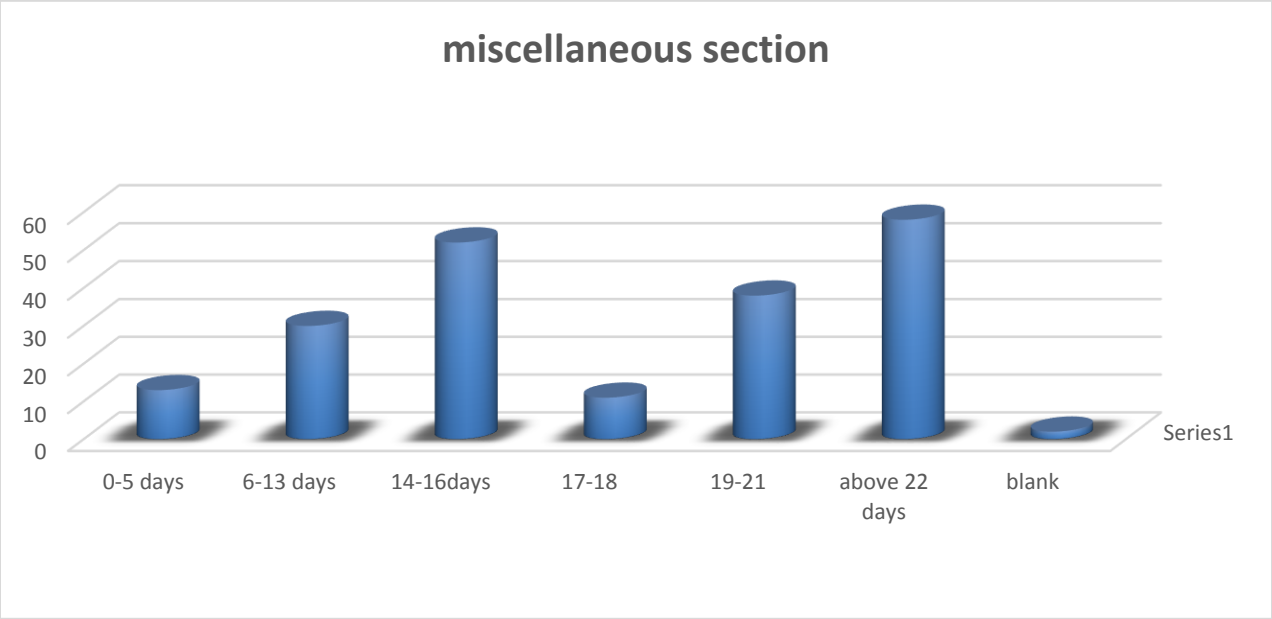
Category	No. of drugs found
Standard (13 days)	3
Above the standard (after 13 days)	159
Below the standard (before 13days)	40



Interpretation: - The standard time for the miscellaneous section is 13 days when the sample is sent from the warehouse.

1. only 1% drugs are found up to the standard.
2. 79% drugs are found above the standard (they take more than 13 days)
3. 20% drugs found below the standard (they take less than 13 days)

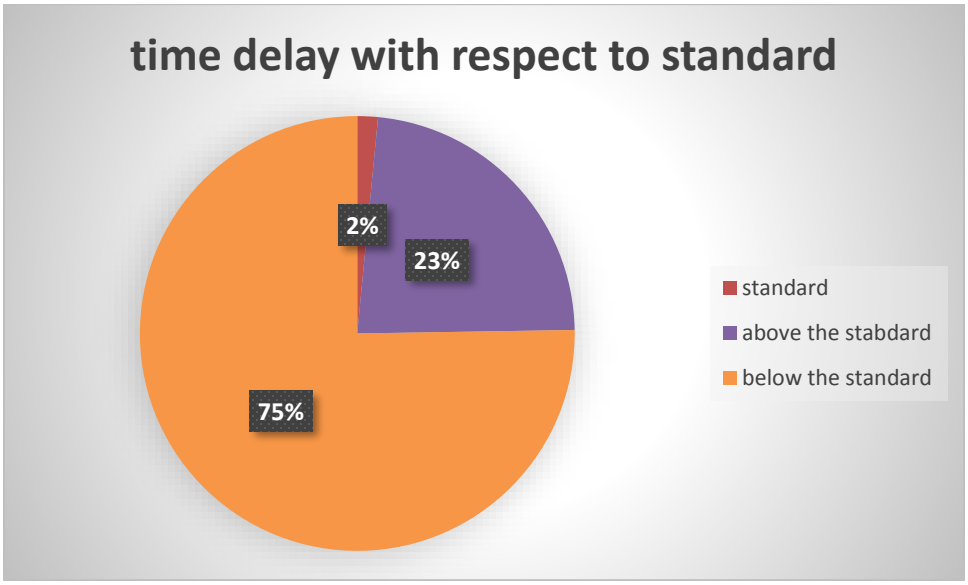
No. of days	No. of drugs found
0-5 days	13
6-13 days	30
14-16days	52
17-18	11
19-21	38
above 22 days	58
blank	2



Inference: - the data is combined as in group of days as we know that the non-sterile product takes 13 days but some are the drugs which take more than 13 days and the no. of drugs which take more than 13 days are more as compared to other group of days.

Surgical

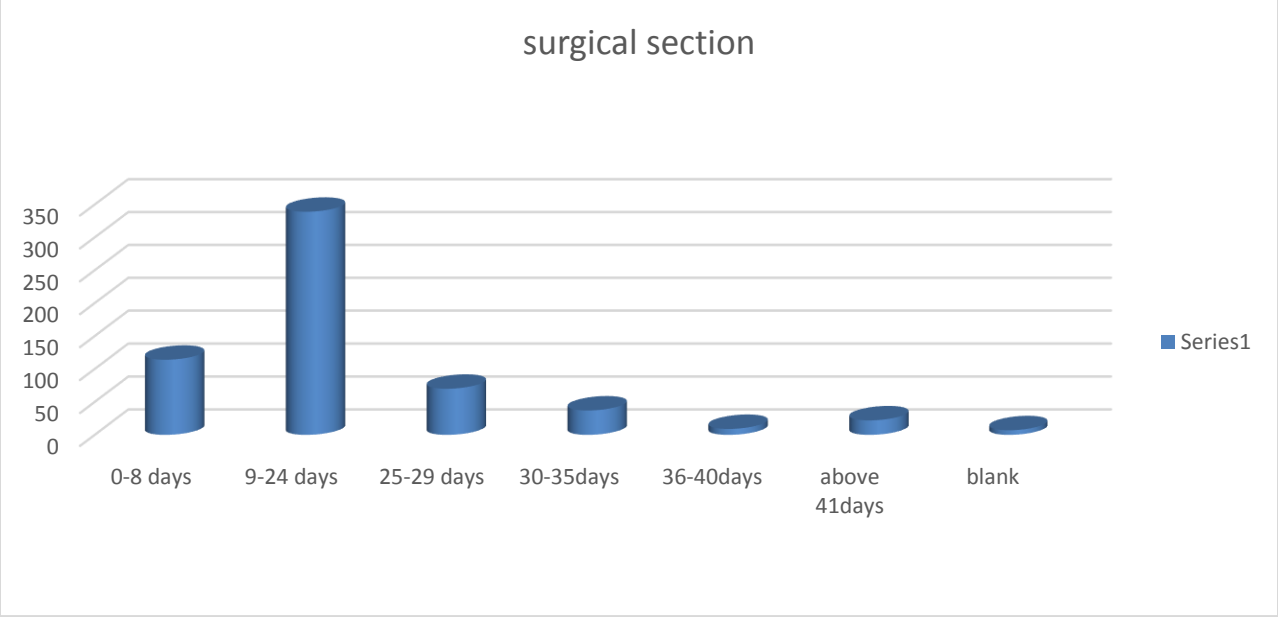
category	No. of drugs found/products
Standard (24days)	9
Above the standard (after 24days)	137
Below the standard (before 24days)	444



interpretation: - The standard time for the surgical section is 24 days when the sample is sent from the warehouse.

1. only 2% drugs are found as per the standard.
2. 23% of products were found above the standard (they take more than 24 days) and
3. 75% are below the standard (means they take less than 24 days to produce result)

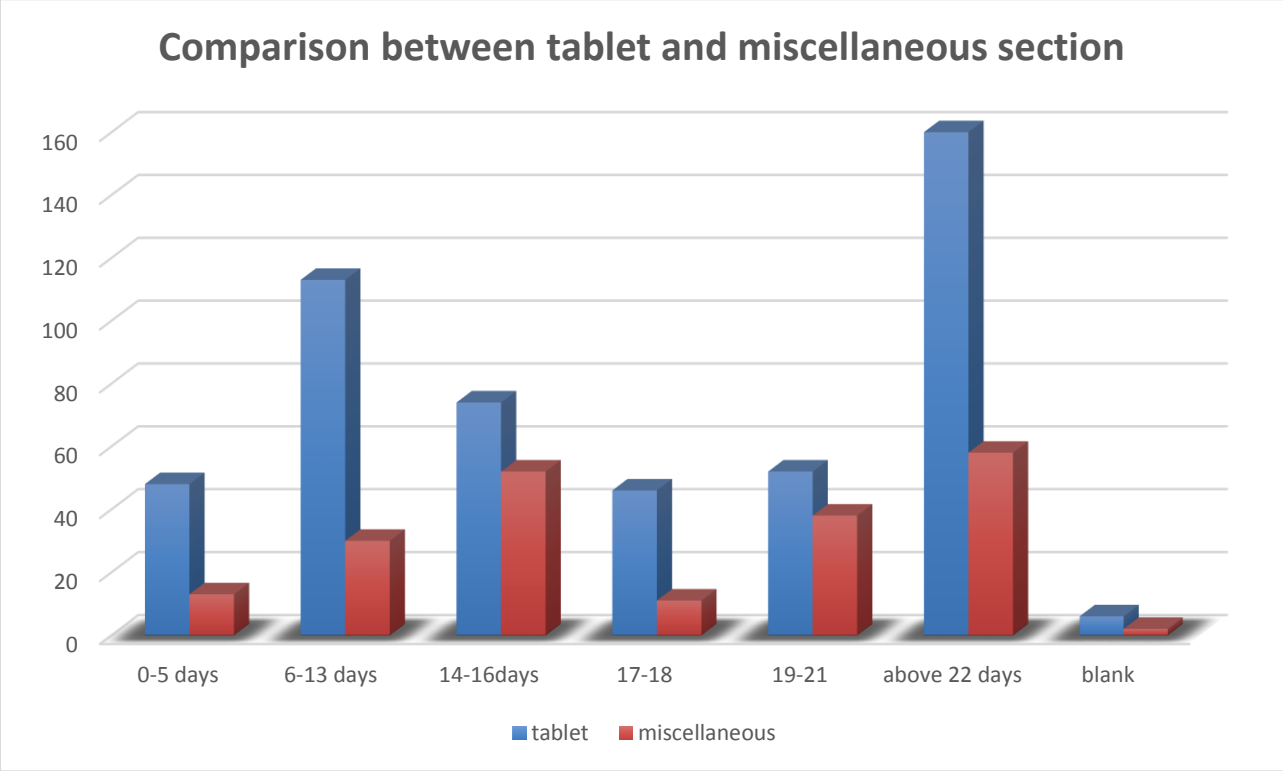
No. of days	No. of drugs found
0-8 days	114
9-24 days	339
25-29 days	70
30-35days	37
36-40days	9
above 41days	22
blank	7



Inference: - the data is combined as in group of days as we know that the sterile product takes 24 days but some are the drugs which take more than 24 days and the no. of drugs which take less than 24 days are more as compared to other group of days

Comparison between tablet section and miscellaneous section

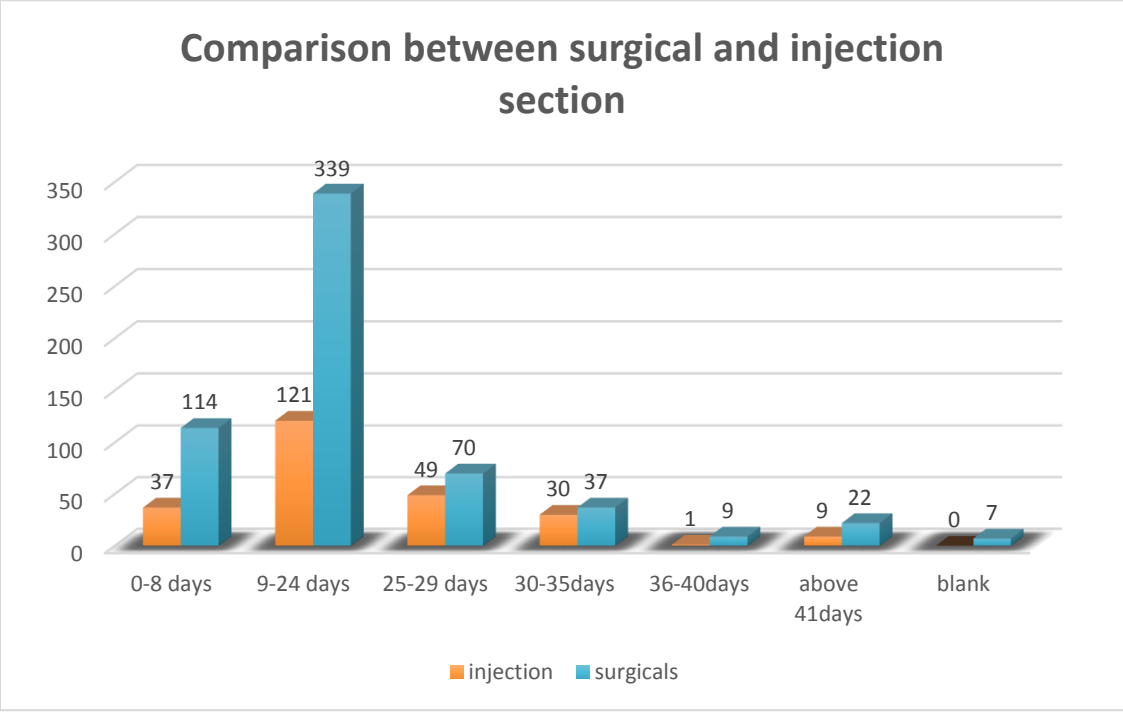
days	tablet	miscellaneous
0-5 days	48	13
6-13 days	113	30
14-16days	74	52
17-18	46	11
19-21	52	38
above 22 days	160	58
blank	6	2



Inference: - As the non-sterile products take 13 days as a standard so we combined the tablet section and the miscellaneous section because both are the non-sterile product as we see the miscellaneous section takes less time to prove their substandard as the tablet section take more time for the approval of medicines.

Comparison between injection section and surgical section

days	injection	surgical
0-8 days	37	114
9-24 days	121	339
25-29 days	49	70
30-35days	30	37
36-40days	1	9
above 41days	9	22
blank	0	7



Inference: - As the sterile products take 24 days as a standard so we combined the injection section and the surgical section because both are the sterile product as we see the injection section takes less time to prove their substandard as the surgical section take more time for the approval of medicines/equipment's.

Pre-Dispatch Testing of Drugs Analyses Report

Many delays have been observed from the time of drug received at the warehouse till the reports received for the quality testing. Keeping in view the mentioned problem, a Pre-Dispatch Testing (PDT) of drugs analyses was conducted for the drugs received from 1 January 2017 to 31 March 2017 (three months). A brief report has been prepared enumerating the results of the analyses done.

Conclusion: -

1. The total number of drugs taken is 1575 (as per E – Aushadhi) out of which 600 are in surgical section, 204 are in miscellaneous, 246 are in injection and 525 are in tablet & capsules section.
2. It was found that of the total 1575 items, sample send request was generated for **1127 items**. 448 items sample send request was not generated out of which 140 are surgical, 60 are miscellaneous, 79 are injectable and 169 are tablet capsule.
3. The total of **135 drugs** were found for which samples have not been sent out of the 1127 items for which sample send request was also generated. Section wise it is 79 in surgical, 11 in miscellaneous, 15 in injection and 30 in tablet capsule.
4. A total of 16 drugs were found for which samples has been send for testing but the results are still awaited (as per E-Aushadhi records).
5. The report also interprets the time taken between the sample send request received and sample sent for testing. 362 samples out of 1127 items were reported to be send after 30 days and more days from the time when request was received**. 164 drugs** testing samples were send after 60 days and **44 drugs** were found with the duration of 100 days and above.
6. The time difference from the sample send for testing and test report received is standardized to 13 days with a relaxation up to 22 days with respective penalty clause for non-sterile items and standardized duration of 24 days with a relaxation up to 41 days with respective penalty clause for sterile items with no deadline specified in the clause.
    - Tablet & Capsule: 6 test reports received in 1 day, 122 reports received within 13 days and 148 reports received in 22 days and above.

- Injectable: 1 test report received in 3 days, 3 reports in 7 days, 121 reports received in 24 days, and 9 reports received in more than 40 days' time.
- Miscellaneous: 32 test reports received in 13 days, 58 reports received in 22 days and above whereas 5 reports were received in 60 days and above
- Surgical: 1 test report received in 1 day duration, 359 reports received in 24 days and 21 reports came after 41 days and above.

- As we see the more drug products are not up to the standard from the data analysis due to this the delay in time becomes the most important factor for not supplying the product. As in delay in supply processes in the supply chain management system.

Limitation

- By this we cannot judge the quality of drug product/item.
- If any problem occurs during the process of the quality assessment this could be unknow to us.
- Data limitation is there because the data is not present in the proper form.
- Analysis is strict in several limits of data.

Recommendation

- The purpose of this study was to develop a performance measurement system for warehouse activities; the system should be based on the quality assessment between standard time interval.
- Assessments should be an opportunity for employee to reflect on their own practice and interpretations, serving either to strengthen employee points of view or to open their mind to other possible interpretations.
- **Recommendations for Improvement**

This section should begin by outlining the strengths of the qualitative product and related to time required for its approval, followed by practical recommendations to improve the weaker areas of the system. These recommendations should be specifically linked to the assessments of quality outlined and related to time required approval of drugs/product and should be feasible and appropriate for the system.