A STUDY ON QUALITY ANALYSIS OF LIST OF QUARENTINE DRUGS AND THE GAPS IN THE APPROVAL OF DRUGS AT GUJARAT MEDICAL SERVICE CORPORATION LTD.

INTRODUCTION

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. The purpose of quality assurance (QA) in public pharmaceutical supply systems is to make certain that each medicine reaching a patient is safe, effective, and of standard quality and provided in time of requirement. QA activities in a hospital or clinic should be comprehensive, spanning the entire supply process from medicine selection to patient use.

OBJECTIVE:

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

Sub objective:

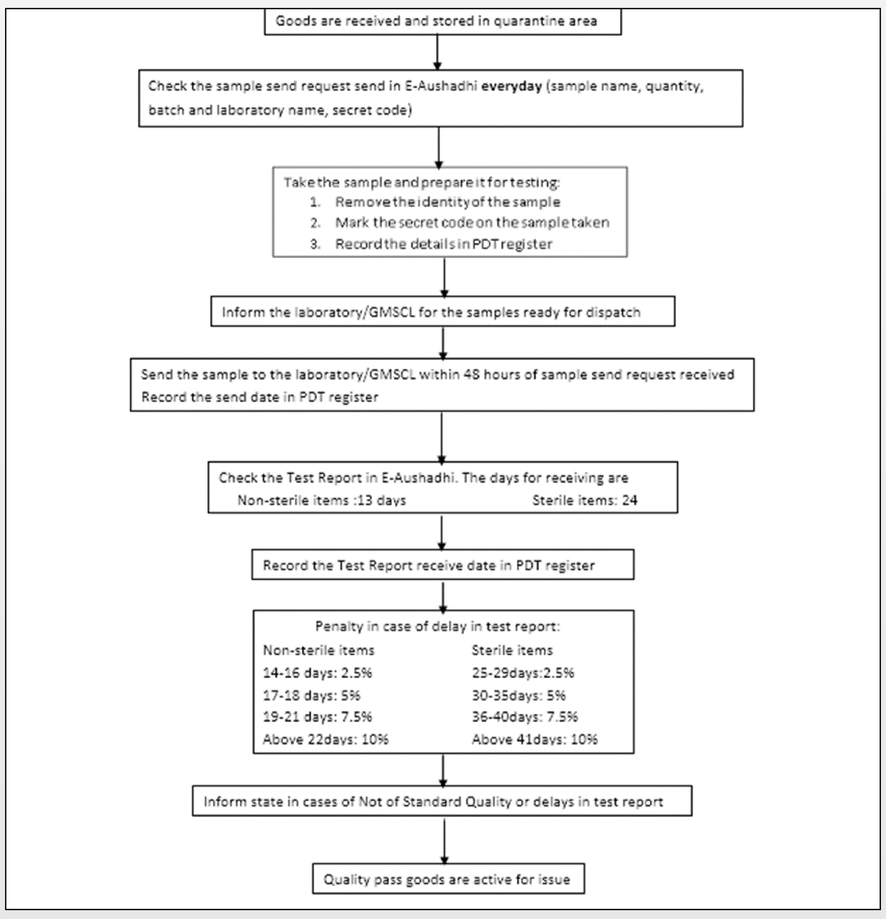
1.To know how many drugs are tested as per the standard guidelines.

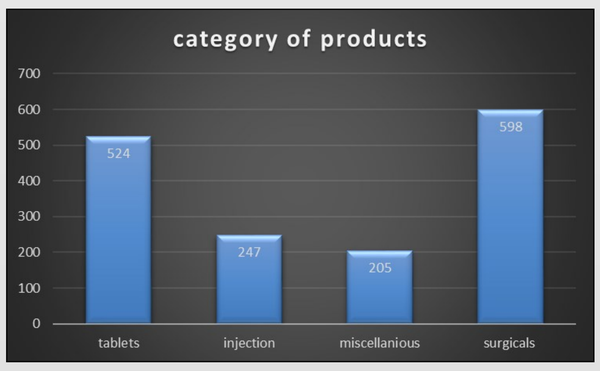
2.The time consumption of drugs in quarantine area. (by comparing with the Standards set by the organization)

Research Methodology

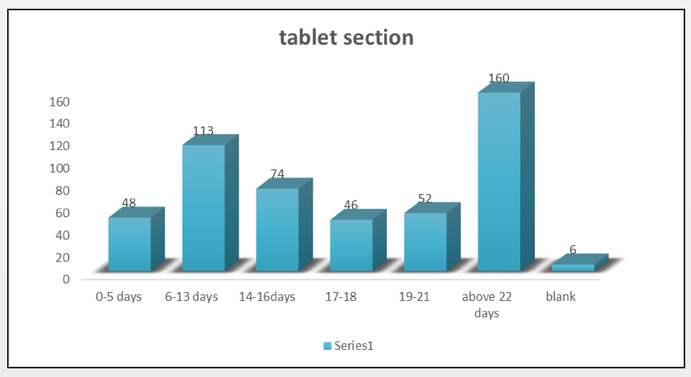
Study design	descriptive
Data collection	Secondary data
Sample size	1576
Sample area	Gandhinagar
Time period of data collection	Jan to march

Activity layout

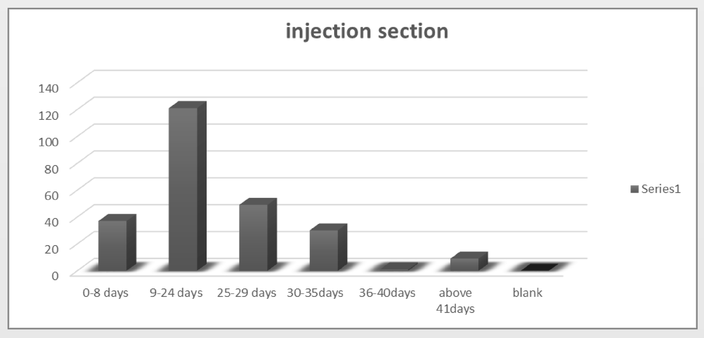




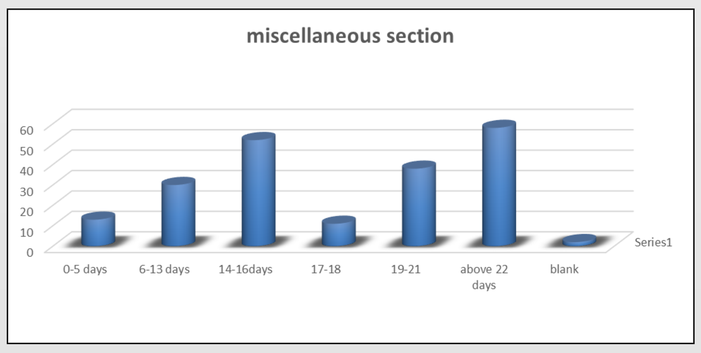
Interpretation: - the total no. of drug product is 1574 we have divided in four categories
Tablet and capsule (524)
Injections (247)
Miscellaneous (205)
Surgical (598)



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.



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.



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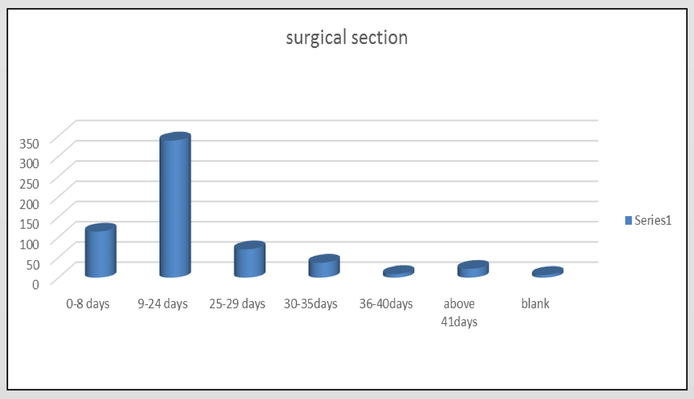

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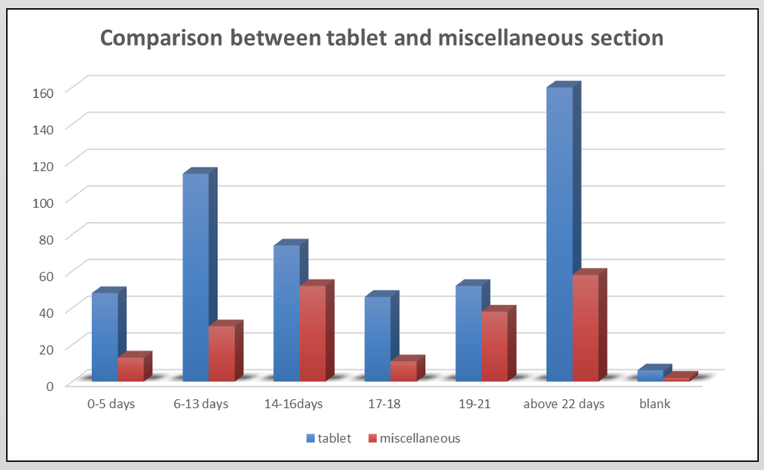
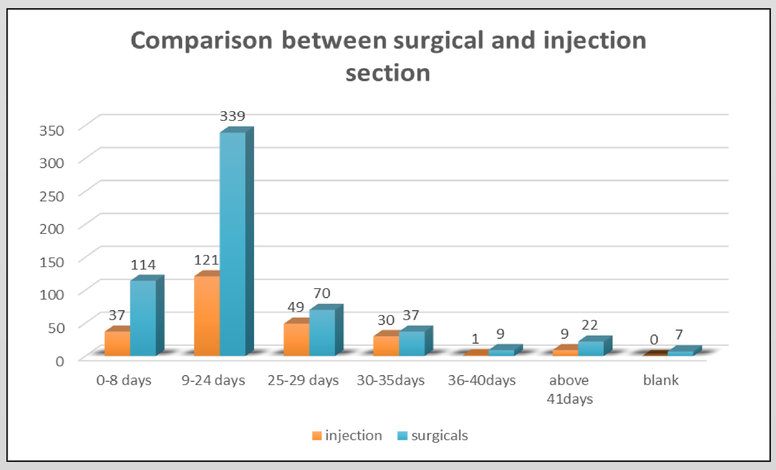


Inference: - As the non-sterile products take 13 days as a standard so we combined the tablet section and the miscellaneous section because both are the non-sterile product as we see the miscellaneous section takes less time to prove their substandard as the tablet section take more time for the approval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



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.

Conclusion

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.

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.