

XYZ Pvt. Ltd.

SAMPLE QUALITY MANUAL AS PER ISO 9001:2000 Std.

Copy No.: Issue No.: 01 Date: xx/xx/xxxx

QUALITY MANUAL

(BASED ON IS/ISO 9001:2000)

XYZ PVT. LTD.

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DISTRIBUTION LIST

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CONTROLLED Copies of this manual are available at the following locations:-

MANAGER	COPY NO. 1
CERTIFICATION BODY	COPY NO. 2
MANAGEMENT REPRESENTATIVE	COPY NO. 3

Note:-

This Quality Management Manual has been prepared as per the requirements of ISO 9001:2000. The Contents of this manual are the sole property of XYZ PVT. LTD., No part of this manual can be reproduced in part or full without the written permission of the owner.

SECTION 0.2

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AMENDMENT RECORD

AMD. NO.	SEC/SUB SEC. NO.	REV. NO. AND DATE	ISSUE NO. AND DATE	NATURE OF CHANGE	APPROVED By

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SECTION 0.3

QUALITY POLICY

(This is an example only)

Quality and Service to the customer is the motto of XYZ PVT. LTD.,

Date xx/xx/xxxx

Section 0.4

LIST OF ABBREVIATIONS

MR	MANAGEMENT REPRESENTATIVE
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XYZ	XYZ PVT. LTD.
QMS	QUALITY MANAGEMENT SYSTEM
REVS. NO.	REVISION NO.
NC PRODUCT	NON-CONFORMING PRODUCT
DEPTT.	DEPARTMENT
NCR	NON CONFORMITY REPORT
CRF	CHANGE REQUEST FORM

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SECTION-1

1.1 Scope of Quality Management System

The Quality Management System covers all departments/offices except Accounts, Taxation and Finance. This QMS covers all aspects and facets of:

Manufacturing of Vacuum Formed plastic packing.

1.2 Application

This Quality Management System described in this manual is applicable to all products manufactured by XYZ PVT. LTD.

1.3 Exclusions

Clause A.Z.

Clause B.X

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SECTION-2

Company Profile:

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SECTION-3

3.1 Terms and Definitions

All terms and definitions used in this Quality Manual are given in ISO 9000:2000

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This section outlines the Quality Management System of **XYZ PVT. LTD.**, which has been established, documented & implemented as per requirements of ISO 9001:2000. The sequence and interaction of various processes are given in Annexure-II. The criteria required for ensuring the effective operation and control of processes has been identified and documented in form of Work Instructions. Availability of resources is ensured by M R. **XYZ PVT. LTD.**, plans & manages these processes in accordance with QMS.

4.2 Documentation Required

4.2.1 General

The Documentation of Quality Management System includes the following:

- A) Quality Policy and Quality Objectives
- B) Quality Manual
- C) Quality Procedures required as per standard ISO 9001:2000
- D) Work Instructions
- E) Quality Records

4.2.2 Quality Manual

XYZ has established, documented and implemented the Quality Manual which includes:

- A) Scope and application of Quality Management System.
- B) Procedures for establishing Quality Management System.
- C) Interaction and interrelation of processes (Annexure-II)

The Quality Management System follows, all mandatory procedures required by ISO 9001:2000.

4.2.3 Control of Documents

The procedure for control of documents XYZ /QP1/4.2.3/R-00 gives details for establishment and implementation of documents which includes:

- A) Approval of documents for adequacy before issue.
- B) Reapproval of documents after updation/review.
- C) Identification of current revision status of documents.

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- D) Availability of documents at the point of use.
- E) Legibility and identifiably of documents.
- F) Distribution of documents.
- G) Identification/marking of "OBSOLETE" when retained for reference purpose.

4.2.4 Control of Records

The Management of VI has documented Procedure for control of records (XYZ /QP2/4.2.4/R-00), which contain guideline for identification, storage, protection, retention period and disposal of all quality records.

Records are maintained to provide evidence of conformity to the requirements and effective operation of Quality Management System. The list of records maintained by XYZ are as under:

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Section-5

5.0 Management Responsibility

5.1 Management Commitment

Top Management of **XYZ PVT. LTD.** is committed for the development & implementation of the quality management system and continually improving its effectiveness by:-

- A) Communicating to the Company personnel, the importance of meeting customer requirements.
- B) Establishing Quality Policy.
- C) By establishing Quality Objectives at relevant levels.
- D) Conducting management reviews
- E) Ensuring the availability of resources.

A well considered quality policy and quality objectives are established and explained to company personnel by management representative. Company has provided adequate resources required to maintain & continually improve effectiveness of its quality management system.

5.2 Customer Focus

Top Management of the organization ensures that customer requirements are determined and are fulfilled with the aim of enhancing customer satisfaction. Customer is considered a focus point while developing policies & business operation strategies. Management Representative ensures that needs and expectations of the customer are formally determined, well understood by commercial & technical personnel and are converted into requirements and are fully met with the aim of achieving customer confidence.

5.3 QUALITY POLICY

XYZ PVT. LTD. has established and documented the Quality Policy in accordance with Quality Objectives of the company.

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Quality Policy has been communicated to employees verbally and through distribution of Quality Policy cards & by displaying at prominent places in the organization. The purpose of Quality Policy has been explained to all employees.

QUALITY POLICY

5.4 Planning

5.4.1 Quality Objectives

Top Management of **XYZ PVT. LTD.** has defined & established Quality Objectives with measurable index wherever possible.

S.No	OBJECTIVES	INDEX
1	AA	xx
2	BB	yy
3	CC	zz
4	DD	uu
5	EE	vv

5.4.2 Quality Management System Planning

The Quality Management System is planned to meet the requirement of ISO 9001:2000 and also the quality objectives defined by the organization. The documented quality management system is the result of planning and in line with quality objectives of the company.

The management further ensures that the integrity of the QMS is maintained whenever any changes to the system are planned & made.

5.5 Responsibility, Authority & Communication

5.5.1 Responsibility and Authority

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Key Personnel:

- pppppppp
- ssssssssss
- zzzzzzzzzz
- mmmmm
- xxxxxxxxxx

5.5.1 Responsibility and Authority

The organization structure is shown at Annexure-I of this Quality Manual. This structure simply shows functional relationship and responsibilities. This does not imply relative seniority of importance of the position.

The responsibility of each individual is made known to him/her separately to understand his/her duties and some are detailed below:

Properitor:

-

CEO(MR):

-

Manager 1:

-

Production in charge/ forman:

-

Manager 2:

- a

5.5.2. Management Representative

CEO of the company has appointed himself as a Management Representative. MR is responsible and authorized for implementation of requirements of Quality Management System.

A)

5.5.3 Internal Communication

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Appropriate communication processes regarding Quality Management System & It's effectiveness, are established within the organization. Management ensures such communication regarding effectiveness of quality management system take place as required from time to time. QMS and its changes are communicated to company personnel by distributing hard copies of documents of relevant part of QMS to concerned persons. The concerned internal auditor communicates internal audit findings to the auditee. Findings of external audits are communicated to the auditee by external auditors/MR.

5.6 MANAGEMENT REVIEW

5.6.1 General

Top management reviews the implementation of quality management system, at planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review covers, evaluation of the need for changes, to this system, organization's quality policy and quality objectives.

5.6.2 Review Inputs

The inputs for the management review include the current performance and opportunities for improvements on the following:

- A) Follow up action from previous reviews.
- B) Result of audit reports.
- C) Customer feedback.
- D) Process performance and product conformity.
- E) Status of preventive and corrective actions.
- F) Planned changes that could affect quality management system such as issues related to quality policy and objectives suitability and effectiveness of quality system.
- G) Recommendation for improvement.
- H) Any other issue.

5.6.3 Review Outputs:

The outputs from the Management reviews include actions relating to:

- A) Improvement of the effectiveness of the quality management system and it's processes.
- B) Improvement of product related to the customer requirements.
- C) Allocation of resources for various needs.
- D) The proceedings of the management review meetings are recorded in the form of minutes and extracts circulated to concerned functionaries for action if required.

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Section-6

6.0 Resource Management

6.1 Provision of Resources

XYZ PVT. LTD. determines and provides in a timely manner, the resources needed:

- A) To implement, maintain and improve the quality management system and continually improve its effectiveness.
- B) To enhance customer satisfaction by meeting the customer requirements.
- C) Resources such as machines, equipments, trained personnel, and process control equipments.

6.2 Human Resources

6.2.1 General

The organization has a define system of recruitment CEO assigns the duties to the personnel on the basis of their education, training, skill and experience.

6.2.2 Competence, Awareness and Training

6.2.2.1 Training needs of all personnel are identified for imparting training after checking the training records (XYZ/MR/010)

6.2.2.2 In-House Training programmes are arranged/organized to enhance the performance level of employees to meet the Quality objective.

6.2.2.3 Appropriate record of education, training, skills and experience are maintained. (XYZ /MR/010,016)

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6.3 Infrastructure

The organization also determines, provides and maintains the requisite infrastructure of facilities for achieving conformity of product including:-

- A) Buildings, workspace and associated utilities.
- B) Process equipments.
- C) Suitable trained personnel (including qualified & trained personnel from outside sources).
- D) Transport and communication facilities.

References:

List of machines- XYZ /PRD/001

Machine breakdown record- XYZ /PRD/002

6.4 Work Environment

Company identifies and manages the work environment necessary to achieve conformity to product requirements. Following working environment needs have been identified as important for achieving conformance of products:

- First aid box
- Fire extinguishers
- Proper light
- Timely tea and lunch break
- Toilets

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Section-7

7.0 Product Realization

7.1 Planning of Product Realization

Product realization is that sequence of processes and sub-processes required for achieving the product quality. Company plans quality assurance of the product to meet the specified requirements which include:-

- A) Quality objectives and requirements of the product.
- B) Quality Assurance plans for the product.
- C) The records evidencing the realization of the processes and conformance of the resulting product, fulfils requirements is maintained.
- D) Company determines product realization processes & acceptance criteria, through specification/drawing given by the customer.

Reference:

Quality plan for incoming inspection for raw material- XYZ /QC/001

Quality plan for final inspection for raw material- XYZ /QC/002

7.2 Customer Related Processes

7.2.1 Determination of requirements to the product

Manager determines the requirements of customers that include the followings:

- A) Product requirements including feasibility and delivery as specified by the customer.
- B) Product requirements necessary for specified or intended use by the customer.
- C) Additional requirements related to the product as decided by the company.

7.2.2 Review of Requirements related to product

Manager reviews the requirements of the customers related to the product, together with additional requirements. The records of such reviews are maintained.

This review is conducted prior to the commitment for supply of product to the customer (e.g. submission of quotation, acceptance of a contract or order), to ensure following:

- a) Product requirements are defined.

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- b) Contract or order requirements differing from that previously expressed are resolved.
- c) The organization has the ability to meet the defined requirements.

7.2.3 Customer Communication

Company identifies and implements, effective arrangements for communicating with the customer relating to following:

- A) Product information.
- B) Product inquiries.
- C) Product requirements and delivery schedules
- D) Customer feedback including customer complaints.

It is ensured that, wherever product requirements are changed, the relevant documents are amended and the concerned persons are made aware of the changed requirements. Records of costumer complaints are maintained.

7.3 Design and Development

7.4 Purchasing

7.4.1. Purchasing Process

XXXXXXX controls purchasing processes to ensure that purchased products conform to specified purchase requirements. The type and extent of control applied to the suppliers and purchased product depends upon the effect on subsequent product realization processes or the final product. The records of all purchase orders are maintained.

Manager evaluates and selects suppliers based on their ability to supply product in accordance with company's requirement. Evaluation and periodical re-evaluation of suppliers is carried out on the format. The results of evaluations and necessary follow up actions are recorded and maintained.

7.4.2. Purchasing Information

Information relating to the item to be purchased is recorded in the purchase order register after placing the order on the supplier.

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7.4.3 Verification of Purchased Product

The XYZ has implemented, inspection and other activities necessary for verification of the purchased product vis a vis the specified purchase requirements.

The inspection records of all incoming material are maintained by Quality Control.

7.5 Production & Service Provision.

7.5.1 Control of Production & Service Provision

Manager plans and controls all manufacturing operations as applicable:

- A) Making available, information that describes the characteristics of the product.
- B) Availability of work instructions, as necessary.
- C) Using and maintaining suitable plant and machinery. Machine breakdown records are maintained (VI/PRD/002) and preventive maintenance is planned and carried out. Records of preventive maintenance are maintained.
- D) Availability and use of the measuring and monitoring devices.
- E) Implementing of monitoring and measurement.
- F) The implementation of release, delivery and post-delivery activities.

7.5.2 Validation of Processes for Production & Service Provision

MANAGER ensures validation of processes at his level. Such validations are carried out, to demonstrate the ability of the processes to achieve the planned results. The organization defines and makes all arrangements for validation of the processes which include the following as applicable:

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- A) Criteria for approval and review of processes are defined.
- B) Equipment and qualification of personnel is approved.
- C) Methodology and procedures are defined.
- D) Required records are maintained.
- E) Revalidation.

7.5.3 Identification and Traceability:

Company identifies, where appropriate, the product by suitable means product realization. All categories of finished products are stored at a unique place in the store for the purpose of identification.

7.5.4. Customer property:

This clause has been excluded from the manual because company does not take any thing from customer.

7.5.5. Preservation of Product:

XYZ PVT. LTD. preserves the conformity of the products, including constituent parts, with the customer requirements during internal processing and delivery to the intended destination. This covers identification, handling, packaging, storage and protection. The stock records of "A" category items are maintained in stock register.

7.6 Control of Monitoring and Measuring Devices

XYZ PVT. LTD. do not use any monitoring measuring devices because this is not a product requirement. So this clause is excluded under permissible exclusion of ISO standard.

Section-8

8.0 Measurement, Analysis and improvements

8.1 General

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XYZ PVT. LTD. has defined plans and implements the monitoring measurement, analysis and improvement processes needed:

- A) To demonstrate conformity of the product.
- B) To ensure conformity of quality management system.
- C) To continually improve the effectiveness. This includes the determination of the applicable methods including statistical techniques and the extent of their use wherever appropriate.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

The organization does monitor information relating to customer satisfaction and as one of the measurements of performance of the quality management system. The organization also monitors information relating to customer perception for fulfillment of customer requirements. The records of customer satisfaction are maintained.

There are two inputs for measurement of customer satisfaction:

- Customer complaints
- Customer feedback form, repeated order from active customer show s the customer satisfaction.

References:

Customer Satisfaction Survey- XYZ /MR/012

8.2.2 Internal Audit

A)

8.2.3 Monitoring and Measurement of Process

The results of the processes are monitored to verify the ability of the process to deliver plan results. In case any deficiency is observed, appropriate corrective action is taken according to procedures for corrective action. (XYZ /P5/8.5.2/R-00)

8.2.4 Monitoring and Measurement of Product

- 8.2.4.1 Inspection is carried out during the manufacturing process in order to achieve the specified requirement of the product.

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8.2.4.2 Semi-finished items are released for next stage if they are found conforming to the requirements.

8.2.4.3 The Finished product is checked for all parameters before it is released for dispatch. The inspection record of in process and finished product are maintained.

8.3 Control of Non-Conforming Product

Foreman & Manager ensures that product which does not confirm to the requirements is identified and controlled to prevent unintended use or delivery.

The organization deals with non-conforming products in one or more of the following ways:

- A) By taking action, to eliminate the detected non-conformity.
- B) By authorizing its use, release or acceptance under authorized concession by a relevant authority and where applicable by the customer.
- C) By taking action to preclude its original intended use or application.

Records of nature of non-conformities and subsequent action taken, including concessions obtained, are maintained.

8.4 Analysis of data

Wherever appropriate M.R. collects and analyzes data to determine the suitability and effectiveness of the quality management system and to evaluate where continual improvements of the QMS can be made. This includes data generated, a result of monitoring & measurement and from other relevant sources. He analyses this data, to provide information on:-

- A) Monitoring for suitability, effectiveness and training.
- B) Characteristics and trends of the processes and product including opportunities for preventive action.
- C) Customer satisfaction.
- D) Conformance to product requirements.
- E) Characteristics and trends of processes including opportunities for preventive action and suppliers.

8.5 Improvements

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8.5.1 Continual Improvement

XYZ PVT. LTD. plans and manages the processes necessary for the continual improvement of the effectiveness of quality management system and facilitates the continual improvement of quality management system through the use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

8.5.2 Corrective Action

Documented procedure XYZ /QP5/8.5/R-00 has been established to deal with observed Non-conformity in order to prevent their re-occurrence where appropriate the Non-conformities are analyzed to detect the root cause. The suggestions are implemented to prevent their re-occurrence for improvement. Records of actions initiated/taken is maintained and reviewed

8.5.3 Preventive Action

Documented procedure XYZ /QP/6 has been established to eliminate the causes of potential Non-conformities with a view to take appropriate action to prevent their occurrence. Records of actions initiated/taken is maintained and reviewed.

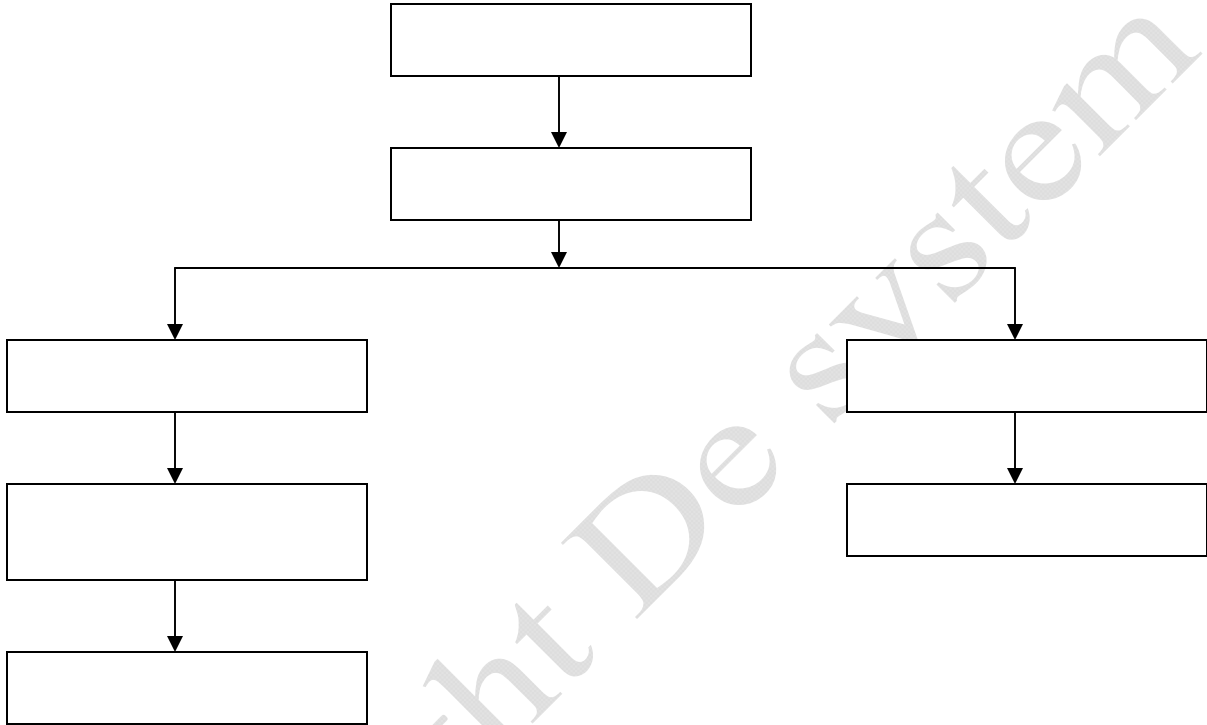
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Annexure-I

ORGANIZATION CHART



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Annexure-II

IDENTIFICATION OF PROCESSES

- XXXXXXXXXXXX
- XXXXXXXXXXXX
- XXXXXXXXXXXX
- XXXXXXXXXXXX
- XXXXXXXXXXXX

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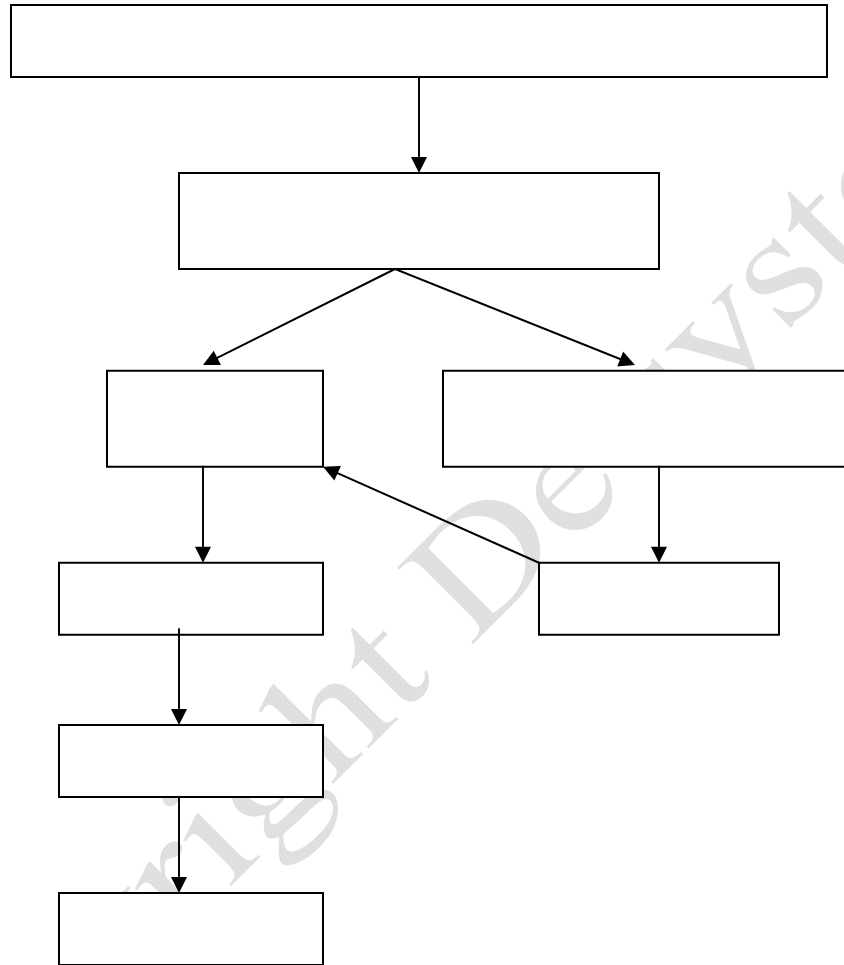
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PROCESS FLOWCHART



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Annexure-IV

LIST OF PROCEDURES

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Annexure-V

LIST OF RECORDS

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