DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Quality Management Review	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Quality Management Review (QMR).

2.0 SCOPE:

This SOP is applicable to Quality Management Review (QMR) for all Department at ……...

3.0 RESPONSIBILITY:

QA (Officer/Executive): Preparation, Distribution, Revision, Retrieval and Destruction of this SOP.
QA Manager)/Head Quality: Review, Training and effective implementation of this SOP to all concerned Departments.
Respective Departments (Head): Training and effective Implementation of this SOP.
Management Review Team: Review and effective Implementation of this SOP.

4.0 ACCOUNTABILITY:

Head Quality: Approval, Authorization, ensure Training and Implementation of this SOP

5.0 DEFINITIONS:

Quality Management Review (QMR): is the review of Quality Management System with regard to its periodical observation, effectiveness and suitability of Quality System and to ensure that the Quality Management System and Production Satisfies Regulatory Requirements, F&D and Supply Chain Quality Policies and Objectives. Quality Management review should provide assurance that objectives of process performance and product quality are met over the lifecycle.

6.0 PROCEDURE:

6.1 Quality Management Reviews include reviews of Quality and compliance issues with products, processes and / or systems at external sites that perform activities under contract for Manufacturing, F&D, Analytical Testing.

6.2 This standard does not directly apply to Management Reviews performed by external sites, but may be used as guidance for assessing them.

6.3 Site QMR Meeting shall be initiated by Head Quality.

6.4 QMR Meeting shall be conducted as per planner shown in **Annexure-I**, Titled **"Quality Management Review Planner"**.

6.5 Head QA shall plan the QMR Meeting in consultation with Head Quality and Director/Management Representative and shall intimate to following Department Heads or any concerned personnel, through mail prior meeting but not limited to:

- Production
- Quality Control
- Engineering
- Warehouse
- Regulatory Affairs
- Purchase/ Finance
- PPIC.

6.6 Director of company may depute his representative for QMR Meeting.

6.7 Following topics shall be covered in QMR Meeting, but not limited to:

6.7.1 **Status of actions on recommendation and findings of prior Quality Management Review (s):** If there are any findings or recommendations in previous QMR, then these shall be included in discussion for their current status and implementation of recommendations.

6.7.2 **Market Complaints:** Implementation of /Adherence to respective SOP, Number of complaints received and increase or decrease in complaints from previous meeting, class and nature of complaint, Repeated complaints, effectiveness of CAPA taken against Root causes, Trend Analysis shall be included in Review.

6.7.3 **Deviations:** Implementation of /Adherence to respective SOP, Number of Deviations raised and increase or decrease in deviations from previous meeting, Type/Category of deviations, Repeated Deviations, effectiveness of CAPA taken for avoid reoccurrence of deviations.

6.7.4 **Incidents:** Implementation of /Adherence to respective SOP, Number of Incidents and increase or decrease in incidents from previous meeting, Repeated Incidents of same type, effectiveness of CAPA taken against Root Cause and Trend of Incidents shall be included in review.

6.7.5 **Change Control:** Implementation of /Adherence to respective SOP, Number of Change Controls, Type /Category of Change Control.

6.7.6 **CAPA and CAPA effectiveness Review:** Implementation of /Adherence to respective SOP, Effectiveness of CAPA.

6.7.7 **Trainings and Effectiveness:** Implementation of /Adherence to respective SOP, effectiveness of Training, Trainer Qualification, any external Training provided, Number of training provided from Last Review Meeting against scheduled trainings and Number of unscheduled training, Training against CAPAs/Complaints/Non conformities/Deviations etc.

6.7.8 **Non Compliances and Audit Findings:** Total Audits faced (Self Inspection, Customer Audits, Regulatory Audits) and total Critical/Major/ Minor observation from last review meeting, compliance reports sent, Total open and closed compliances, total/type of queries from Auditor after compliance.

6.7.9 **Area/Equipments Qualification:** Implementation of/Adherence to respective SOP, any new/periodic/requalification performed, challenges during performance, Implementation of recommendations given in Qualification Reports.

6.7.10 **Environmental Monitoring:** Implementation of/Adherence to respective SOP, challenges during performance, any deviation observed in Environmental Monitoring (Temperature, Relative Humidity, Microbial excursion etc.) parameters in any area from last review meeting.

6.7.11 **Process/Cleaning/Method Validation:** Implementation of/Adherence to respective SOP, any new/periodic/re-validation performed, challenges during validation, Implementation of recommendations given in Validation Reports.

6.7.12 **Vendor Qualification:** Implementation of /Adherence to respective SOP, total vendor audited/qualified/rejected from last review meeting.

6.7.13 **Quality Agreements with external Agencies or Customers:** Implementation of /Adherence to respective SOP, Total Number of Quality Agreements from Last Review Meeting.

6.7.14 **OOS/OOT Results:** Implementation of/Adherence to respective SOP, Total OOS/OOT results observed and investigated, Cause (s) of OOS/OOT.

6.7.15 **APR:** Status of Annual Product Review and product related observations shall be reviewed.

6.7.16 **Recall:** All recalls (if any) or Mock recall (if performed) from last review meeting shall be considered in Management Review meeting.

6.7.17 **Technology Transfer:** Details of Products transferred from other manufacturing location through technology transfer from last Quality review meeting, challenges in Technology transfer shall also be included in review.

6.7.18 **Self Inspection/Regulatory Inspection/Customer Audits Status:** Non conformance, observations, suggestions of Self Inspection/Regulatory Inspection/Customer Audits along with taken / proposed /Open CAPA shall be included in review.

6.7.19 **Introduction of New Documents:** It includes all new SOPs, Protocols, STPs, Manuals and other procedures including status of respective change control.

6.7.20 **Status of Quality Issues:** It includes quality issues related to Finished Products, API, Excipients, Packaging Materials, MLT/Sterility failure, exceeding Alert/Action Limit and rejected Batches etc.

6.7.21 **Status of EHS Report:** it includes the observed issues and their CAPA, related to Environment Health & Safety.

6.7.22 **Pharmacopoeial/Guideline Updation:** It include status of Updation in Pharmacopoeia/ Guideline, change affected documents/procedure and introduction of new guideline.

6.7.23 Status of key strategic goals (Business and Quality) and associated key performance indicators.

6.7.24 Changes in product ownership; e.g., changes in product registration, changes in the location of product manufacturing, testing, packaging, Introduction of new product in facility, etc.

6.7.25 Overall Review Status of QMS including Data integrity, any overdue (e.g. CAPA etc.), open Deviation, Change Control, Complaints and Compliance etc.

6.7.26 Review adequacy of resources to ensure the implementation and maintenance of the QMS and continually improve its effectiveness. Inadequacy of resources can be indicated by, for example, missed timelines for CAPA or late investigations.

6.7.27 **Risk Assessment Status:** Impact on the quality, safety, therapeutic efficacy of products, Recurrence of product issues, Status of determination of root cause of product or process issues, Failure to follow Quality System; e.g., any kind of Deviation, Inefficiencies in the Quality System, Supply chain impact.

6.8 The calendar year start from 1st of Jan of the year and data shall be considered up to 31st December of year.

6.9 Year to Date (YTD) shall be calculated and reviewed for Corrective and preventive action.

6.10 In the QMR, data of previous review meetings shall be presented.

6.11 A global review of 12 Months Quality Indices Matrix shall be reviewed carefully by categorizing the Quality Indices. So as a global Corrective Action and Preventive Action shall be planned wherever necessary.

6.12 Written status shall be provided by the respective personnel in review meeting and shall be filed with Management review record.

6.13 Attendance record of all participants shall be maintained in format as per **Annexure-II**, Titled **"Attendance Record for QMR"**.

6.14 Minutes of meeting shall be prepared by Officer/Executive QA, Reviewed by Manager QA and Approved by Head quality as presented in **Annexure-III**, Titled **"Minutes of Meeting of Quality Management Review"**, describing the achievements, status of previous recommendations of QMR, conclusion of current QMR meeting and recommendation to meet out the Quality policy or standards of the organization

6.15 Minutes of meeting shall be sent by QA to the Director/Management Representative, Head Quality for reference and to all the concerned personnel of Plant for further improvement as per QMR recommendations through CAPA (wherever applicable).

6.16 Remedial Corrective action shall be taken by respective department based on QMR recommendations.

6.17 A certificate as shown in **Annexure-IV**, Titled **"Site Management Review Certificate"** shall be issued from management after satisfactory review of Quality Management System in format.

6.18 The official copy of Site Management Review materials and **'Minutes of Meeting'** and **'Site Management Review Certificate'** shall be filed and retained in QA.

6.19 Each Quality Management Review shall be recorded in format as shown in **Annexure-III**.

6.20 **Frequency:**

6.20.1 Quality Management Review Meeting shall be conducted by Head quality under the administration of Management Representative at Plant on **Quarterly ± 15 Days** basis.

7.0 ABBREVIATIONS:

API	Active Pharmaceutical Ingredient
APR	Annual Product Review
CAPA	Corrective Action & Preventive Action
EHS	Environment Health and Safety
Ltd.	Limited
MLT	Microbial Limit Test
No.	Number
OOS	Out of Specification
OOT	Out of Trend
PPIC	Production Planning and Inventory Control
Pvt.	Private
QA	Quality Assurance

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Quality Management Review Planner	
Annexure-II	Attendance Record for QMR	
Annexure-III	Minutes of Meeting of Quality Management Review	
Annexure-IV	Site Management Review Certificate	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.
- Controlled Copy No. 05 Engineering Department.
- Controlled Copy No. 06 Warehouse Department (Store).

10.0 REFERENCES:

- Draft Guidance on Guidance for Industry: Data Integrity and Compliance with cGMP April 2016
- PIC/S: Guide to Good Manufacturing Practice for medicinal products; PE 009-13 (Part I); 1 January 2017
- ISO 9001: 2015 Quality Management System Guidance Document.
- Draft Guidance on Guidance for Industry: Submission of Quality Metrics Data Rev. 01, November 2016.
- ICH Q10 Pharmaceutical Quality System June 2008.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I
QUALITY MANAGEMENT REVIEW PLANNER

Year: **Frequency:** Quarterly ± 15 days

S.No.	QMR Schedule	Administered By (Name)		Actual Execution Date	Remark (if any)
	Quarterly	Head Quality	Management Representative	Quarterly	

Remark (If any):

Prepared By:
Officer/Executive QA
(Sign & Date)

Checked By:
Manager QA
(Sign & Date)

Approved By:
Head Quality
(Sign & Date)

ANNEXURE-II
ATTENDANCE RECORD FOR QMR

Date: **Meeting Time:** **Meeting Venue:**

S.No.	Name of Employee	E. Code	Department	Designation	Sign & Date

Manager QA:
(Sign & Date)

Head Quality:
(Sign & Date)

Management Representative:
(Sign & Date)

ANNEXURE-III

MINUTES OF MEETING OF QUALITY MANAGEMENT REVIEW

Date of QMR Meeting	
Status of Previous recommendations of QMR	
Next QMR Meeting Schedule	

S.No.	Recommendation	Responsibility	TCD	Remarks

Conclusion:

Prepared By:	Reviewed By:	Approved By:
Officer/Executive QA	Manager QA	Head Quality
(Sign & Date)	(Sign & Date)	(Sign & Date)

ANNEXURE-IV

SITE MANAGEMENT REVIEW CERTIFICATE

Date:

Site Management Review of the …….., Location …… have been performed and following topics have been reviewed.

- Status of actions on recommendation and findings of prior Management Review (s)
- Market Complaints
- Deviations
- Incidents
- Change Control
- CAPA and CAPA effectiveness Review
- Trainings and effectiveness
- Non compliances and Audit Findings
- Area/Equipments Qualification
- Environmental Monitoring
- Process/Cleaning/Method Validation
    - Vendor Qualification
    - Quality Agreements with external Agencies or Customers
    - OOS/OOT Results
    - APR
    - Recall
    - Technology Transfer
    - Self Inspection/Regulatory Inspection/Customer Audits Status
    - Introduction of New Documents.
    - Status of Quality Issues.
    - Status of EHS Report.
    - Pharmacopoeial/Guideline Updation.
    - Status of key strategic goals (Business & Quality) and associated key performance indicators.
    - Changes in product ownership; e.g., changes in product registration, changes in the location of product manufacturing, testing, packaging, etc.
    - Overall Status Review of QMS including Data integrity, any overdue (eg. CAPA etc.), open deviation, change control, complaints & compliance etc.
    - Review adequacy of resources to ensure the implementation and maintenance of the QMS and continually improve its effectiveness. Inadequacy of resources can be indicated by, for example, missed timelines for CAPA or late investigations.

- Risk Assessment Status
- Others (Please Specify)

This is certify that the overall status of the Site Quality Management System are fulfilling the Quality Objectives and meets the National and International regulatory requirements for manufacturing of Products as per cGMP norms.

Head Quality:
(Sign & Date)

Management Representative:
(Sign & Date)