DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
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1. **Purpose:** The purpose of this SOP is to describe the procedure for working of Quality Council.

2. **Scope:** This SOP is applicable for Quality Council meeting discussions involving but not limited to; Quality System performance, Quality system indices, Process Performance and Product quality of commercial, new and transferred products in the facility at ……..

3. **References, Attachments & Annexures:**

3.1 **References:**

3.1.1 In House

3.2 **Attachments:**

3.2.1Attachment-1: Attendance Sheet for Quality Council Meeting

3.2.2Attachment-2: Minutes of Meeting of Quality Council

1.1 **Annexures:**

3.3.1Annexure-1: QA Monthly Report

3.3.2Annexure-2: QC Monthly Report

3.3.3Annexure-3: QA Monthly report quality parameter calculation

3.3.4Annexure-4: QC Monthly report quality parameter calculation

4. **Responsibilities:**

1.1 **QA Designee:**

4.1.1To prepare the QA monthly report.

4.1.2To calculate QA monthly report Quality Parameter.

1.1 **QC Designee:**

4.2.1To prepare the QC monthly report.

4.2.2To calculate QC monthly report Quality Parameter.

1.1 **QC Head:**

4.3.1To identify non-compliance cGMP discussion points.

4.3.2To provide inputs related to critical system findings and possible action plan in view of cGMP.

4.3.3To review the QC monthly report.

1.1 **QA Head:**

4.4.1 To identify non-compliance cGMP discussion points.

4.4.2To provide inputs related to non-compliance system findings and possible action plan in view of cGMP.

4.4.3To track the proposed action plan.

4.4.4 To review the QA monthly report

1.1 **Quality Head:**

4.5.1 To arrange the meetings of Quality council.

4.5.2To identify non-compliance cGMP discussion points.
4.5.3To identify Quality Council team members.
4.5.4To present non-compliance cGMP discussion points during Quality Council meeting.
4.5.5To approve the QA and QC monthly reports.
4.5.6To approve QA and QC monthly report Quality parameters calculation.
4.5.7To escalate required information of non-compliances and related activities to regional operation head and Corporate Quality Head.
4.5.8To ensure that a timely and effective communication and escalation process exists to raise quality issues to regional operation head and Corporate Quality Head.
4.5.9To prepare and circulate Quality Council meeting minutes.
4.5.10To assure compliance of proposed action plan from global Quality council meetings.
4.5.11 To review and approve the SOP.

1.1 **Other Department Heads (Production/Maintenance/P & A/EHS/Warehouse):**

4.6.1To identify non-compliance cGMP discussion points.
4.6.2 To provide inputs related to critical system findings and possible action plan in view of cGMP.
4.6.3To take the necessary actions as per the Quality Council minutes of meeting.

1.1 **Corporate Quality designee:**

4.7.1 To review QA monthly and QC monthly reports and provide the comments.

1.2 **Plant Head:**

4.8.1To attend and lead the team during Quality Council meeting (as a chair person).
4.8.2To ensure that a timely and effective communication and escalation process exists to raise quality issues to the regional quality council.
4.8.3 To arrange, monitor and provide resources for compliance of actionables from regional quality council meeting.
4.8.4 To review and approve the SOP.

4.9 **Regulatory Affairs:**

4.9.1 To review and approve the SOP.

4.10 **Corporate Quality Head:**

4.10.1 To provide the monthly QA and monthly QC report formats.

5. **Distribution:**

1.1 Quality Assurance
1.2 Quality Control
1.3 Production
1.4 Maintenance
1.5 Ware House

1.6 Packing
1.7 EHS
1.8 Personnel & Administration

6. **Abbreviations and Definition of Terms:**

Abbreviations:

6.1.1 CC No.: Change Control Number
6.1.2 FDD: Formulation and development
6.1.3 SOP: Standard Operating Procedure
6.1.4 OOS: Out of specification
6.1.5 CAPA: Corrective action and preventive action
6.1.6 TCD: Target Completion Date
6.1.7 BMR: Batch Manufacturing Record
6.1.8 BPR: Batch Packing Record
6.1.9 cGMP: Current Good Manufacturing Practice
6.1.10 CQ: Corporate Quality
6.1.11 MOM: Minutes of Meeting
6.1.12 QA: Quality Assurance
6.1.13 QC: Quality Control
6.1.14 QRB: Quality Review Board
6.1.15 Sr. No.: Serial No
6.1.16 Inst.: Instrument
6.1.17 P&A: Personnel and Administration
6.1.18 EHS: Environment, Health and Safety
6.1.19 OOT: Out of Trend

6.9**Definition of Terms :**

6.2.1 **Quality Council:** Quality Council is a forum at every manufacturing location consisting of factory management who convene for discussions involving but not limited to; quality system performance, quality system indices, process performance and quality of products manufactured and owned by the site.

7.**Procedure:**

7.1 **Introduction:**

7.1.1The Quality Management System is a web of interdependent systems, and performance matrices for each system must be carefully evaluated to maintain the integrity of each system.

7.1.2In order to evaluate the Quality performance matrices periodically in consistent manner, Quality Council shall be formed.

7.1.3Quality Council is

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7.1.3.1A forum for leadership engagement, awareness and decision-making around quality system and process performance at site.

7.1.3.2 A key governance body to manage potential risks.

7.1.1Quality Council is not

7.1.4.1A substitute for line management accountability.

7.1.4.2The only forum for addressing improvements to quality systems and cGMP problem solving

7.1.4.3A place to work or solve problems.

7.1.4.4A forum to review day to day quality issues.

7.2 **Objectives of Quality Council:**

7.2.1 To schedule periodic agenda based meeting for deriving collective solution to the cGMP issue in discussion.

7.2.2 To monitor the actionables and target dates derived in Quality council meeting until resolution of the issue.

7.2.3 To escalate the repetitive cGMP risks/critical cGMP compliance risk to management for discussion in regional quality council meeting.

7.3 **Quality Council Team Members:**

7.3.1The quality council is a high level forum to support the premise that the Quality Council is a mechanism to exercise management responsibility as well as to ensure timely decisions and cross-functional support.

7.3.2The quality council shall be formed by the Quality Head.

7.3.3The quality council team shall consist of highest level of each function. Highest level of each function shall be permanent team member of Quality Council e.g.

7.3.3.1Quality Head

7.3.3.2 Factory Head

7.3.3.3 CQA

7.3.3.4 QA Head

7.3.3.5 Production Head

7.3.3.6 QC Head

7.3.3.7 Maintenance Head

7.3.3.8 Materials Management, Packaging Development Department (PDD) and Formulation Development Department (FDD) Head

7.3.3.9 Warehouse Head

7.3.3.10 EHS Head

7.3.1Based on agenda, need based participants can be invited for Quality council meetings by Quality Head.

7.3.2Plant Head shall be the chairperson of the Quality council.

7.4 **Frequency:**

7.4.1Quality council meeting shall be held once in a month.

7.4.2In case of critical cGMP Quality risk, Quality Council meeting can be requested by any Quality council permanent member at any time with the concurrence of the Quality Head.

7.5 **Agenda of Quality Council Meeting:**

7.5.1 The Quality Head shall prepare the agenda for Quality Council meeting based on,

7.5.1.1Critical findings from Monthly report Quality Indices.

7.5.1.2 Action items from previous Quality Council Meeting.

7.5.1.3 Emerging regulation changes/new technology introduction.

7.5.1.4 Other avenues of cGMP improvement such as regulatory audit observations/customer audit observations/internal audit observations/warning letter or similar serious observations to other companies by regulatory agencies.

7.5.1.5 CQ comments.

7.5.2In order to discuss Quality Indices of each Quality System parameter effectively in Quality Council meeting, thorough monthly report shall be prepared by each site.

7.5.3Monthly report shall constitute evaluation and Quality Indices calculation of following systems (Annexure 1 and Annexure 2).

7.5.4**Weightage for each parameter shall be given based on criticality i.e. risk to cGMP compliance.**

7.5.4.1**QA Monthly Report**

7.5.4.1.1 24 x 7 Compliance

- Events and incidents
- Batch Failure
- Change Control
- Self Inspection/Internal Audit
- APR (Annual Product Review)
- Planned Modification
- Corrective action and Preventive action
- Document Review (BMR and BPR)
- CQ document implementation (CQ Directive and CQ Guideline)
- Location SOPs
- Market Complaint
- Training

7.5.4.1.2 Plant up keeping 24X7

- Plant up keeping
- Daily observation (On-line)/QA oversights

7.5.4.1.3External Audit

7.5.4.1.4 Scale up/Validation issues

7.5.4.2 **QC Monthly Report**

7.5.4.2.124x7 Compliance

- Productivity
- Total sample (Raw material/Finished Product/Intermediate/Packing Material/Process Validation/Cleaning Validation) pending for release
- Release Cycle Time
- Repeat Analysis
- OOS/OOT
- Review of QC documents
- Instrument Utilization
- Any analytical error/Proposed CAPA

7.5.4.2.1 QC up keeping 24x7

- QC up keeping
- Daily observation

7.5.4.2.1 External Audit

7.5.4.2.2Analytical method issues

7.5.5 Explanation for calculation of performance indicators (monthly report) of the quality system is attached as Annexure 3 and Annexure 4.

7.5.6 Each monthly report shall be numbered as per following system

XX-YY-ZZ

Where,

XX = Type of monthly report i.e. QA or QC

YY = Serial No. from 01 to 12 based on month i.e. For January month it is “01”, for February month it is “02” and so on.

ZZ = Last two digits of current year i.e. for the year 2014 it will be “14”.

7.5.7 CQ designee shall review the QA monthly and QC monthly reports and provide the comments for improvement.
7.5.8 Corporate Quality Head shall provide the QA and QC monthly report formats to sites.

7.6 **Working of Quality Council:**

7.6.1 The Quality Head shall circulate the invitation through mail for Quality Council meeting along with an agenda to all permanent members and to need base participants.
7.6.2 The invitation shall be sent at least 24 hours prior to the meeting.
7.6.3 To facilitate the preparation and thorough discussion, monthly report trend charts, additional information if any shall be circulated to the participants in advance.
7.6.4 The attendance sheet shall be filled as given in the attachment-1.
7.6.5 Discussion points identified shall be discussed at length and action plan for mitigation shall be exercised with emphasis on prioritization of specific area e.g. administrative action, budget approval etc.
7.6.6 Discussion points shall be presented in clear and concise manner so that they are understood easily by all the participants e.g. by preparing power point presentation, graphical presentation etc.
7.6.7 Responsibilities and target completion date shall be clearly identified during meeting and action shall be initiated based on outlined action plan.
7.6.8 Any critical cGMP issue other than those listed on the agenda can also be discussed if required but it shall be discussed only after the original agenda items are discussed.
7.6.9 Quality Head or designee shall prepare MOM of Quality Council meeting and shall circulate MOM in timely manner to,

- All the participants
- Operation Heads
- CQ Head

7.6.10 QA Head or designee shall track the action plans periodically for the closure.

7.6.11 In all subsequent meetings progress based on earlier Quality council meetings shall be reviewed and further action plan and responsibilities shall be exercised if needed with due justification.

7.6.12 The Quality Head has the final authority in decisions affecting cGMP.

7.6.13 Minutes of meeting format for Quality council meeting is attached as attachment no. 2.

7.6.14 Original copy of minutes of meeting of Quality Council shall be appropriately archived.

7.6.15Meeting agendas and minutes from the Quality Council meeting are “privileged and confidential” documents under general internal audit programs. These documents are not eligible for external regulatory review unless approved by the Quality Head and Factory Head. Documents may be redacted, as necessary, prior to producing for external regulatory review.

7.7 **Notification to Regional Quality council:**

7.7.1The critical issues which can cause serious compliance/business risk shall be identified in Quality council meeting and escalated immediately to regional operations Head and Corporate Quality Head.

7.7.2The outcome of escalated points shall be documented.

7.8 **Meeting Numbering System:**

7.8.1 **Meeting numbering system for Quality Council Meeting:**

Example: First meeting of July shall be numbered as:

JUL/21/001,

where JUL denotes first three alphabets of month like JUL means July.

14 denotes 2021

001 denotes serial no. of meeting

Month	Month denotes for meeting numbering system
January	JAN
February	FEB
March	MAR
April	APR
May	MAY
June	JUN

Month	Month denotes for meeting numbering system
July	JUL
August	AUG
September	SEP
October	OCT
November	NOV
December	DEC

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Attachment – 1

Attendance Sheet for Quality Council Meeting

Location: **Page No.:**

Date: **Meeting Number**:

S.No	Name	Employee Code	Designation	Department	Signature

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Attachment – 2

Minutes of Meeting of Quality Council

Location: **Page No. :**

Date: **Meeting Number:**

MINUTES OF MEETING

S.No.	Discussion Points	Action Plan	Target completion date	Responsible person

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Pending Points of Last Quality Council Meeting:

S.No.	Pending Points of Meeting No	Discussion Points	Action Plan	Responsible person	Reason for Pending	Target completion date

Improvement Done in Last Quality Council Meeting:

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Recommendations for Improvement:

Prepared By (Name):
Sign & Date:

Checked By (Name):
Sign & Date:

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Annexure – 1

QA Monthly Report

Name of the Location: **Monthly Report No:** **Version:**

Note: This Annexure should be prepared as same format of SOP in Excel Sheet.

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Annexure –2

QC Monthly Report

Name of the Location: **Monthly Report No:** **Version:**

S.No.	Parameters	Weightage	Breakup Activity	Quarterly Baseline (Nos.)	%	Objective (2020-21)	Unit of Measurements	Total Nos. of Lab Errors OOS/Repeat	Actual in Q1	% Achievement wrt Objective	% Sum of Achievement	Quality Index	Action Taken	Constraint/ Remarks

Note: This Annexure should be prepared as same format of SOP in Excel Sheet.

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Annexure – 3

Monthly report is designed to evaluate the existing cGMP system of plant against predefined performance indicators.
Report consists of 4 section namely,

1. 24x7 Compliance
2. Plant up keeping 24x7
3. External Audit
4. Scale up/validation issues

Monthly report consists of total performance Weightage of 100 %. Performance Weightage are distributed in each section as follows,

S.No.	Monthly Report Section	Weightage
1	24x7 Compliance	40 %
1.1	Events and Incidents	7 %
1.2	Batch failure	8 %
1.3	Change control	5 %
1.4	Planned modification	3 %
1.5	CAPA	3 %
1.6	Document review (BMR & BPR)	3 %
1.7	CQ document implementation (CQ Guideline and CQ Directive)	3 %
1.8	Location SOPs	2 %
1.9	Market Complaint	6 %

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Sr. No.	Monthly Report Section	Weightage
2	**Plant up keeping 24X7**	**40 %**
2.1	Plant up keeping	30%
2.2	Daily observation (on-line)/QA oversights	10%
3	**External audit**	**10 %**
4	**Scale up/Validation issues**	**10 %**
Total		**100%**

There are three types of calculations used in monthly reports.

Type-I calculation: Higher the count lowers the marks.

Type-II: Higher the count higher the marks

Type-III: Other calculations.

Annexure – 3

Type -1 Calculation

Type-1 calculation is explained by taking the example of "Total Individual Batch failures in a month" in monthly report.

Step No.	Description	Calculation
1.	In "weightage" column of the monthly report weightage of the particular parameter is given. Weightage is given based on criticality of Quality parameter.	No calculation required. e.g. For batch failure activity weightage given is 8%.
2.	In "actual in monthly" column actual number of batch failures in a month shall be stated.	No calculation required. e.g. 3 batch failures were given in a month.
3.	Based on the information % Batch failures with respect to total number of batches manufactured in a monthly shall be calculated.	= Number of batch failures x 100 / Total number of batches manufactured in a month. If total number of batches manufactured in a month are 400 then calculation will be as follows:

Step No.	Description	Calculation
3.		3 x 100/400 = 0.75.Thus % Batch failures in a month is 0.75%.
4.	Marks obtained for the parameters shall be calculated. Global target for batch failure is NMT 0.5% wrt total number of batches manufactured.	= 100 x target/ % achieved 100 x 0.5/0.75 = 66.67% The marks obtained are 66.67%
5.	For Total marks of particular parameter , sum of all sub parameters of respective parameter shall be done	For example Parameter = Batch Failure Sum of Individual marks achieved for below mentioned sub-parameters shall be done 1) Total Batch Failure (66.67) 2) Root cause identified (90) 3) Repetitive Type (75) 4) Investigation Closure beyond time-line (85) 5) Total Open (Beyond time line) (85)

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Step no.	Description	Calculation
5.		Total marks achieved for parameter "Batch Failure" = 66.67 + 90 + 75 + 85 + 85 = 401.67
6.	Quality Index calculation. Basis for Quality Index calculation is weightage.	Quality Index = weightage x Total Marks / 100 x total of sub parameters As per above mentioned "Sr. No. : 5" for Batch failure data 8 x 401.67 / 100 x 5 = 6.4267 Thus Quality index for Batch failures is 6.43
	This calculation is applicable for following parameters in, **Monthly Report:** Closure beyond time-line (Cumulative) Repetitive Type Total Open Cumulative (Beyond time line) Batch failure Investigation Closure beyond time-line (Cumulative)	

Step no.	Description	Calculation
	Repetitive Type, (Batch Failure) Investigation Closure beyond time-line (Batch Failure) Total Open (Beyond time line) (Batch Failure) Total Temporary Change Controls raised Total Open Cumulative Change Control (Beyond 3 months) Open of Planned Modification as per the action plan beyond time line (Cumulative) Total CAPA open (beyond time line) (Cumulative) Total No. of open CQ global CAPA (beyond time line) (Cumulative) Total BMR and BPR review observations No. of CQ Directives pending for implementation (Cumulative) No. of CQ Guideline pending for implementation (Cumulative) Revision of SOPs beyond time-line (Cumulative) Total FAR raised	

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Step no.	Description
	Total Recall performed MC Substantiated (Confirmed) Repetitive substantiated market complaints (Last one year complaint shall be considered as repetitive) No. of batches having Scale up/validation problem

Type-2 Calculation

If the Quality system break up parameter is indicative of departure from the target e.g. Root cause identified for event, in that case Type-2 calculation is used.

Type-2 calculation is explained by taking the example of "Events and Incidents – Root cause identified" in a monthly report.

1.	Weightage and actual in month calculation	Step 1 and Step-2 of Type-1 calculation shall be followed.
2.	% Achieved calculation	% Achieved shall be : Actual x 100/ Total no. of events in a month e.g. If actual is 4 in month and total is 5 in a month then % achieved is 4 x 100 /5 = 80. Thus %Achieved is 80%.

3.	Marks obtained calculation	Marks = % Achieved. Thus marks obtained are 80.
4.	Quality Index calculation	Quality Index calculation - Follow step-5 of Type-1 calculation

Type-3: Calculation

1.	During External audit if no. Critical observations found more than 2 then base on conditional formatting mark will be calculated automatically as "0" otherwise it will be "100%".

Overall Quality Index for Monthly Report

1.	Overall Quality Index of QA shall be calculated by adding Quality indices of each quality parameter.	If Quality Index of Batch failure is 26.67, total TCC raised in a monthly is 9.90 and revision of SOPs beyond time line is 10.50. 26.67 + 9.90 + 10.50 = 47.07. Thus 47.07 is the Quality Index of QA in a monthly at particular location. Average of rated number shall be calculated. Average = Sum of rated numbers of all check points / No. of check points. Then Average rating number shall be derived for all assessed plants.

Annexure – 3

1.		Sum of average rating number of individual plants / No. of Plants assessed. Final marks for plant up keeping parameter shall be calculated as follow: Marks = Average rating i.e. compliance level achieved x 100 / 4, Where “4” is the rating for complete compliance i.e. “No actions required”.

Note:	If marks obtained are more than 100% then marks are considered 100% and if marks obtained are in negative then 0% is considered. For this conditional formatting is done in the report.

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Annexure – 4
QC Monthly report quality parameter calculation

Monthly report is designed to evaluate the existing cGLP system of plant against predefined performance indicators. Report consists of 4 section namely,

1. 24X7 Compliance
2. QC up keeping 24X7
3. External Audits
4. Analytical method issues

Monthly report consists of total performance weightage of 100 %. Performance weightage are distributed in each section as follows,

Sr. No.	Monthly report section	Weightage
1.	**24X7 Compliance**	**80 %**
1.1	Productivity	25 %
1.2	Total sample pending for release	7.5 %
1.3	Release Cycle Time	7.5 %
1.4	Repeat Analysis	15 %
1.5	OOS	15 %
1.6	Instrument Utilization	10 %
2.	**QC up keeping 24X7**	**10 %**
2.1	QC up keeping	5 %
2.2	Daily observation	5 %
3.	**External audits**	**5 %**
4.	**Analytical method issues**	**5 %**
Total		**100%**

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Annexure – 4

Calculation

Step no.	Description	Calculation
1.	**Productivity:** Weightage for all the parameters given based on criticality. Objectives are given for each section based on average productivity of year. Actual Q1is average three month productivity of each section. % achievement shall be calculated Quality Index Calculation	 =Productivity (actual Q1)/annual productivity(objective)*100 Quality Index = % sum of achievement*weightage/900*100
2.	Total Sample pending for release. % pending samples against total samples received in Month. % achievement shall be calculated	 Data shall be pick up from monthly report. If % pending is zero then shall get 100%marks otherwise shall be calculated = objective/actual Q1*100

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Step No.	Description	Calculation
2.	Quality Index Calculation	Quality Index = % sum of achievement*weightage/400* 100
3.	Release cycle time Pl refer the calculation from monthly report Quality Index calculation	 Same as monthly reports only weightage 7.5% taken here.
4.	Repeat analysis: % achievement shall be calculated Quality Index Calculation	 Quality Index = % sum of achievement*weightage/200
5.	OOS analysis details: % achievement shall be calculated Enter the no's of OOS closure beyond time	

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Step no.	Description	Calculation
5.	Enter the no's of root cause identified Quality Index:	 Quality Index = % sum of achievement*weightage/300
6.	Instrument Utilization % achievement wrt objective shall be calculated. Quality Index:	 = Average utilization/objectives *100 (if inst. not available enter zero in utilization) Quality Index = sum of achievement*weightage/300
7.	QC Up Keeping % achievement wrt objective shall be calculated. Quality Index:	 = Rating (actual Q1)/4*100 Quality Index = % sum of achievement*weightage/200

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Step no.	Description	Calculation
8.	Daily observation: % achievement wrt objective shall be calculated. Quality Index:	 If % observation wrt total released batches is more then 1 shall get 0% marks otherwise shall be 100% marks Quality Index = sum of achievement*weightage/100
9.	External audits(External audits(Including Corporate compliance) % achievement wrt objective shall be calculated. Quality Index:	 If % No's of major observation is more then 3 shall get 0%marks otherwise shall be 100% marks If % No's of critical observation is more then 2 shall get 0%marks otherwise shall be 100% marks. Quality Index = sum of achievement*weightage/200

Annexure – 4

Step no.	Description	Calculation
10.	Analytical method issues % achievement wrt objective shall be calculated. Quality Index:	 IF % wrt total no of issues raised is equal or more than 20 shall get 100%marks otherwise shall be 0% marks. Quality Index = sum of achievement*weightage/100
11.	Overall Quality Index to be calculated	Sum of all individual quality index of parameters.
Note:	If marks obtained are more than 100%, then marks are considered 100% . For this conditional formatting is done in the report.	

8. History

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