Your Logo Here

[Company]

[Company Address]

ISO 9001:2015

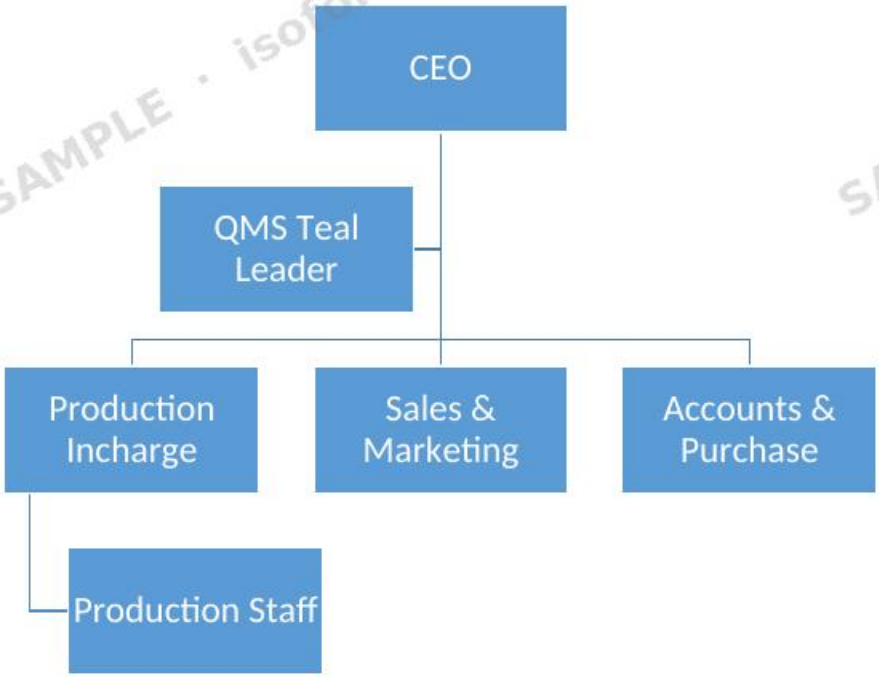
QUALITY MANAGEMENT SYSTEM

(MANUAL)

Prepared By (Name & Sign)	Approved By (Name & Sign)	Date
	[Manager]	
Document No.: M/01	Revision No. 00	Update Date: 01/01/2020

1.2 ORGANIZATION STRUCTURE

Put here your organization structure.



Your Logo Here

[Company]

[Company Address]

ISO 9001:2015

QUALITY MANAGEMENT SYSTEM

CONTEXT OF ORGANIZATION

(PROCEDURE)

Prepared By	Approved By	Date
Document No.: P/01	Revision No. 00	Update Date: 01/01/2020

Contents

1. PURPOSE

The purpose of this procedure is to define how the [Company]'s Strategic Direction is developed by top management through the identification of interested parties, issues of concerns, risks and opportunities. Also to address requirements of ISO 9001 as stipulated under clause 4.1, 4.2 & 6.1.

2. SCOPE

This procedure is applicable to all activities [Company] performs and products which [Company] provides. Including all department and operations being performed by [Company] or outsourced.

3. TERMS AND DEFINITIONS

INTERESTED PARTIES

"Interested parties" person or organization that can affect [Company], be affected by [Company], or perceive itself to be affected by a decision or activity of [Company].

All other applicable as defined in clause 3 of manual.

4. PROCEDURE

4.1 IDENTIFICATION OF EXTERNAL AND INTERNAL ISSUES

All HODs are responsible for identifying internal and external issues on an ongoing bases which can have positive and/ or negative impact on performance of [Company]. These issues shall identified and documented in Manual clause 4.1 and in Risk and Opportunity Analysis Sheet for further processing and actions by QMS team leader. QMS team is responsible for reviewing it and keeping the documents up to date.

4.2 IDENTIFICATION OF INTEREST PARTIES & THEIR CONCERNS

Following the scope of activities defined in manual clause 2, the interested parties shall be defined in clause 4.2 of manual. The parties shall be reviewed and their information shall update when required or at least on annual bases during the management review meeting.

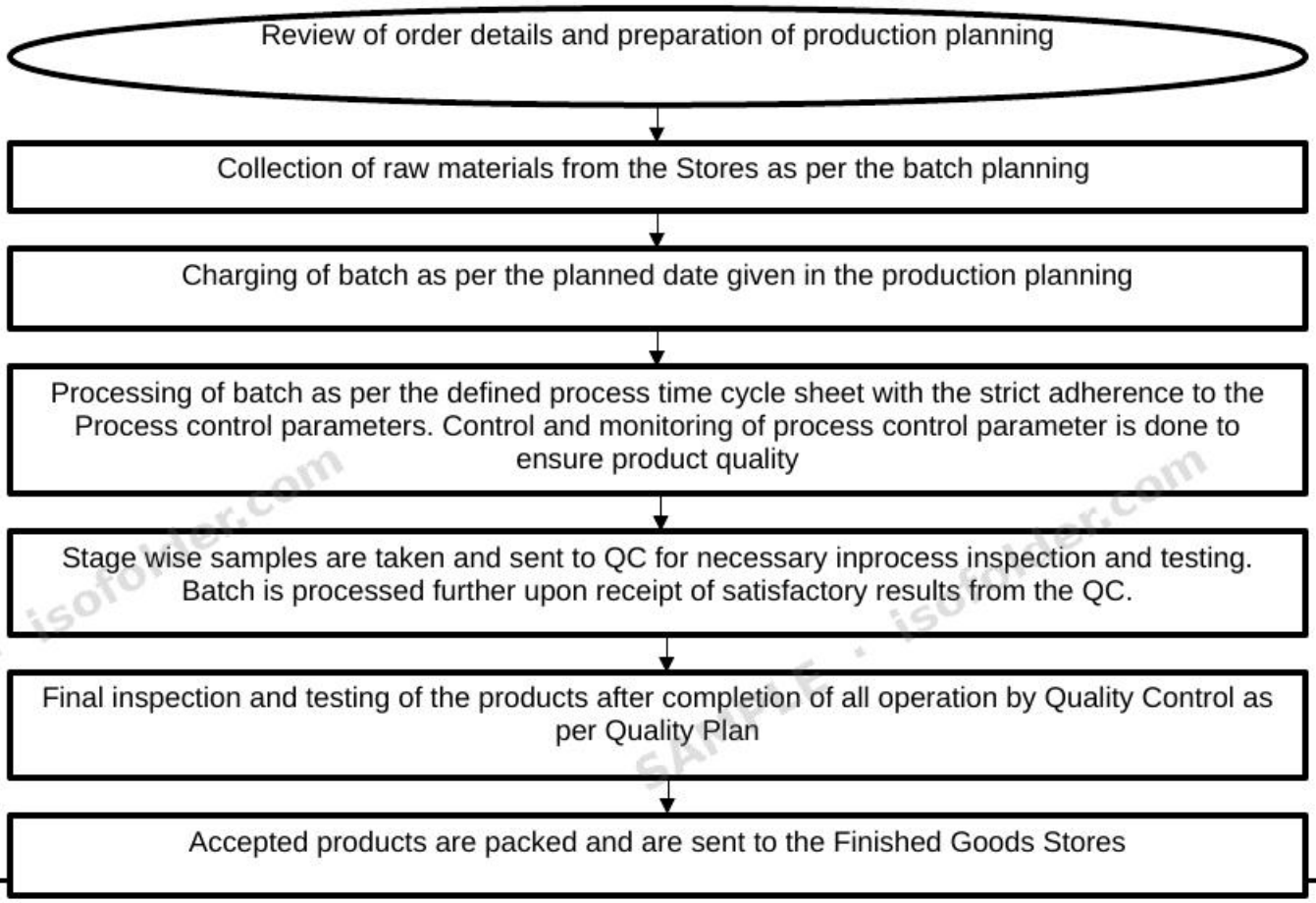
For each interest party, the related issues of concern shall be identified in the Risk and Opportunity Analysis Sheet by QMS team leader with participation of HODs. These issues shall be identified along with the impact they can have on organization, and further actions shall be decided.

Note: When attempting to identify internal concerns, it may be useful to consider technological concerns, employee concerns, etc. When attempting to identify external concerns, it may be useful to consider concerns arising from competition, society and culture, labor relations, statutory and regulatory issues, supply chain, economic issues, etc.

Production

Responsibility	**Production Head / Plant In charges**

Process Flow



[Company]

Objectives & Targets

F/24
Rev No.00

Department →			Year →														
Quantifiable Criteria / Control Parameters	Target		Program to achieve Objective	Results for the month of													
	Present	Future															
Signature Of Functional Heads→																	

Causes for deviation	Actions planned	Target completion	Person responsible	Follow – up actions

ISO 9001: 2015 Clause	ISO 9001:2015 Audit Checklist

REQUIREMENT			STATUS
4. Context Of the Organization			
4.1	**Understanding the Organization and its context**		
	1)	Have you determine external and internal issues in the Quality management system (QMS)?	
	2)	Does this issues are relevant to its purpose and ability to achieve intended outcome of to take Quality management system (QMS)?	
	3)	Have you considered the context of the organization's overall business activities? Does QMS scope cover all the activities or any exclusion for any areas or functions?	
4.2	**Understanding the needs and expectations of interested parties**		
	1.	How many interested parties are identified by you and are relevant to your Quality management system in implementing ISO 9001-2015?	
	2.	What is the requirements of interested parties in Quality management system? What procedure or process is followed to understand interested parties requirements?	
	3.	Have you defined any other quality requirements in the organization?	
4.3	**Determining the scope of the Quality management system**		
	Have you determine the boundaries and applicability of the Quality management system?		
	Have you documented the scope of the organization considering below details?		
	a)	Have you determining this scope of the organization and considered external and internal issues?	
	b)	Do you considered any requirement of interested parties in the scope?	
	c)	Have you considered interfaces and dependencies between activities perform by the organization and other organization?	
	Have you prepared documented QMS scope?		
4.4	**Quality management system and its process**		
	Have you established and implemented QMS in accordance of ISO 9001-2015?		
	How do you establish the QMS?		
	How do you maintain QMS in your organization? What kind of documentations structure is made by you?		
	How do you bring continual improvement in Quality management		

[Company]

Corrective Action Report	F/22 Rev No.00 Page 1 of 1

Sr. No. →		Date →	
Department →			
Non-conformities Identified During			
	Raw-Material Inspection and Testing		Handling of Customer Complaints
	Inprocess Inspection & Testing (Specify the Stage)		
	Manufacturing		Internal Quality Audit
	Final Inspection and Testing		Others, Specify
Description And Cause of Non-conformities (Result of Investigation)			
Description of Non-Conformities			
Root Cause			
Date	Identified By		
Action Recommended			Responsibility
Action Taken			
Date	Taken By		
Summary of Document Change etc.			
Planned Date For Reviewing Effectiveness			
Review Effectiveness of Corrective Action Taken			
Date			Management Representative

Department	Your Company Name	No.	E/QCD/01
Quality Control		Rev No.	00
		Date	01-10-2015

Sr. No.	Product	Parameters	Acceptance Criteria	Sampling	Ref. Document	Record
Incoming Inspection And Testing						
Sr. No.	Product	Parameters	Acceptance Criteria	Sampling	Ref. Document	Record
1.	Raw Materials	• As Per E/QCD/02/XX		50 Ml. / Gms. Per Lot	Test Methods	Sample Test Request
2.	Packing Materials, Spares, Consumable, Misc. Materials	• As Per Requirements, referred in Indent		100 %	Visually	Inward Records
InProcess Inspection And Testing						
Sr. No.	Product / Process Stage	Parameters	Acceptance Criteria	Sampling	Ref. Document	Record
1.	During and after Chemical Reactions	• Parameters as referred in PTC		100 %	Test Methods	Log Sheet / Sample test request slip
2.	After Liquid Standardization	• Strength and Tone	• Product wise acceptance criteria	100 %	Test Methods	Sample test request
3.	After Drying	• Strength and Tone	• Product wise acceptance criteria	100 %	Test Methods	Sample test request
		• Moisture Content	• 5 % Max.			
Final Inspection And Testing						
Sr. No.	Product	Parameters	Acceptance Criteria	Sampling	Ref. Document	Record
1.	Synthetic Organic Dyes	• Strength	• 100 ± 3 %	100 Gms. / Lot	Related Test Methods	Sample test request / Certificate of Analysis
		• Delta E	• 0.5 Max.			
		• pH	• 6.0 – 9.0			
		• Solubility	• 100 GPL			
		• Dusting grade	• 3 – 5			

Prepared By	Approved By	Signature	Page 1 of 1
QC Incharge	**QC Head**		