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

1.0 OBJECTIVE:

To lay down a Procedure for Writing Position Paper.

2.0 SCOPE:

This SOP is applicable to all Plants and Facilities.

3.0 RESPONSIBILITY:

CQA (Operating Person)	**:**	Preparation, Distribution (To Plant-QA and Corporate Departments), Revision, Retrieval and Destruction of this SOP.
CQA (Operating Manager)	**:**	Review, Training (To Plant-QA and other Corporate Departments) and Effective implementation of this SOP.
Plant QA (Operating Person)	**:**	Preparation of Plant SOP in accordance with this SOP and Retrieval of this SOP.
Plant QA (Operating Manager)	**:**	Training and Effective Implementation of this SOP to all Concerned Department of Plant.
Initiator (Concerned Department)	**:**	Initiation of the Position Paper.
Initiating Head Department	**:**	Review of Position Paper.

4.0 ACCOUNTABILITY

Head CQA	**:**	Approval, Authorization, ensure Training and Implementation of this SOP. Approval of Position Paper for all corporate departments.
Head QA	**:**	Training and Effective Implementation of this SOP. Approval of Position Paper at Plant.

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
BPR	Batch Packaging Record
CAPA	Corrective Action and Preventive Action
CQA	Corporate Quality Assurance
GTP	General Test Procedure
Ltd.	Limited
No.	Number
PP	Position Paper

QA	Quality Assurance
RCA	Root Cause Analysis
SOP	Standard Operating Procedure
STP	Standard Test Procedure

6.0 PROCEDURE:

Note:

a) Position Paper is an approach which provides a Platform for back ground situations and a way forward.

b) Under no circumstances position paper shall be used in place of deviation.

6.1 Definition:

6.1.1 **Position Paper:** Position Paper is a tool to enhance or utilize the Quality Management System to make it in-line with Global / Regulatory / Site Specific / Product Specific Requirement etc.

6.2 Each Individual shall be responsible to ensure the Adequacy, Accuracy, Completeness and Correctness of Documentation.

6.3 Position Paper can be initiated to trigger a Deviation / Incident / Change Control / Investigation / CAPA etc.

6.4 In case of any observation found during Audits, Quality Review finding etc. which may or may not have any significant impact on existing system shall be updated through Position Paper.

6.5 Position Paper shall be prepared in following cases:

6.5.1 To meet the Global Regulatory Requirement.

6.5.2 To meet the Site Specific Requirement.

6.5.3 To meet the Product Specific Requirement.

6.5.4 To Enhance the Procedure / System.

6.6 Numbering System for Position Paper:

6.6.1 Position Paper No. for Corporate Departments shall be assigned as **PP/VVV/YY/NNN**,

Where,

PP	**:**	Position Paper
/	**:**	separator
VVV	**:**	Denotes Corporate Department Code (For e.g. CQA, CIT, CHR etc.)
/	**:**	Separator
YY	**:**	Last two digits of the Calendar Year

NNN : Serial No. of the Position Paper raised in current Calendar Year

Note:

For Corporate Department Code refer CQA SOP No. CQA/001 "SOP on SOP".

Example: PP/CQA/21/001 → Denotes first Position Paper No. of CQA initiated in year 2021.

6.6.2 Position Paper No. of Plants shall be assigned as **PP/X/VV/YY/NNN**,

Where,

PP : Position Paper
/ : separator
X : Denotes Plant Code
/ : separator
VV : Denotes Department Code
/ : Separator
YY : Last two digits of the Calendar Year
NNN : Serial No. of the Position Paper raised in current Calendar Year

Note:

a) For Plant code Refer CQA SOP No. CQA/001 "SOP on SOP".

b) For Department Code refer Plant specific "SOP on SOP".

6.7 Preparation of Position Paper:

Note: Any concerned personnel can initiate the Position Paper.

6.8.1 Based on the decision taken by the Head Initiating Department for the need of position paper, the initiating department shall prepare the Position Paper as per format shown in **Annexure-I "Position Paper".**

6.8.2 In case of correction / enhancements needed in corporate related implemented documents, corporate initiating department shall prepare the Position Paper and shall further be reviewed by respective Head of Initiating Department.

6.8.3 In case of correction / enhancements needed in Plant related implemented documents, initiating department of Plant shall prepare the Position Paper and shall further be reviewed by respective Head of Initiating Department.

6.8.4 Numbering of Position paper shall be assigned by CQA/QA to the initiating Department and same shall be logged in **Annexure-II "Position Paper Log"**.

6.8.5 Final Draft shall submitted by initiating department to CQA/QA for print out.

6.8.6 CQA/QA shall take the print out of final copy of position paper and shall send to initiating department for further sign off.

6.8.7 Position Paper shall be sent to Head CQA/QA for review and approval.

6.8.8 Details of Position Paper shall be mentioned by CQA/QA in format as shown in **Annexure-II "Position Paper Log"**.

6.8.9 Photocopy of Approved Position Paper with Reference stamp shall be attached along with the respective document.

6.8.10 Original copy of Position Paper shall be retained in CQA/QA department.

7.0 REFERENCES:

- UNA: United Nation Associates Article of Xavier University Library

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Position Paper	
Annexure-II	Position Paper Log	

9.0 DISTRIBUTION:

- Controlled Copy No. 01 Corporate Quality Assurance
- Controlled Copy No. 12 Corporate Information & Technology
- Controlled Copy No. 13 Corporate Health & Medical Services
- Controlled Copy No. 14 Corporate Pharmacovigilance
- Controlled Copy No. 15 Corporate Environment, Health & Safety
- Controlled Copy No. 16 Corporate DRA
- Master Copy Corporate Quality Assurance

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control Number	Details of Changes	Reason for Change	Effective Date	Updated By

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ANNEXURE–I (Specimen Copy)

LOGO	***X-----** **LOCATION **CORPORATE QUALITY ASSURANCE#**
POSITION PAPER	

Position Paper No: **Date:**

Initiating Dept.:

Objective:

Description:

Attachment (if any):

Initiated By:	**Reviewed By:**	**Approved By:**
Initiating Dept.	**Head Initiating Dept.**	**Head CQA**
(Sign & Date)	**(Sign & Date)**	**(Sign & Date)**

Note: # Incase of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place

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ANNEXURE-II

LOGO	*X----- **LOCATION **CORPORATE QUALITY ASSURANCE#**
POSITION PAPER LOG	

S.No.	Date	Position Paper No.	Initiating Department	Objective	Logged by CQA (Sign & Date)

Note: # Incase of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is location of the plant and place.