SOP FOR PHARMACOPOEIAL AMENDMENTS AND GUIDELINES UPDATES

1.0 OBJECTIVE:

To lay down a Procedure for Pharmacopoeial Amendments and Guidelines updates.

2.0 SCOPE:

This SOP is applicable to Updation of Raw Material Specification, Finished Product Specification, Validation Procedures, Environmental Monitoring Procedures, Manufacturing Procedure, Analytical procedure and other Critical Parameters which affect the Quality & efficacy of the product due to change / Updation in National / International Pharmacopoeia & Guidelines from the regulatory bodies at all manufacturing Location.

3.0 RESPONSIBILITY:

Executive QA

4.0 ACCOUNTABILITY:

Head QA

5.0 PROCEDURE:

5.1 Any change or new updation in Pharmacopoeia & Guidelines shall be identified by QA Department.

5.2 QA Department shall depute a senior person of the Department to update the Specification, Protocol, Procedures and any other parameters which affect the Quality and Efficacy of the Product as or when there is Revision, Addendum or Publication of New Guidelines from National & International Regulatory Body.

5.3 QA Department shall maintain the record of all the Addendum of different Pharmacopoeias and Guidelines in the record.

5.4 QA shall follow the current version of SOP **"Change Control"** SOP for updation or change in any Specification & Procedure.

5.5 Any change or updation of Procedures / Specification, QA shall revise the RM / Finished Product Specification / Protocols as recommended by the Pharmacopoeia / Guideline / FDA circulation.

5.6 Updated Specification, Protocol & Procedure shall be with reference of related document such as Pharmacopoeia and Guidelines published by various Regulatory Authorities.

5.7 QA shall withdraw the old Specification / Protocol / Procedure from the Concerned Department as per Respective SOP and QA shall issue new version of Specification / Protocol / Procedure to the Concerned Department.

5.8 It is responsibility of QA & Concerned Department at site to ensure timely evaluation of proposed changes in the Specification; Protocol & Procedure user Department is also responsible for evaluation of the impact of the proposed changes on the existing system (s) and initiate measures on the same.

5.9 QA shall also inform to customer about Changes.

5.10 QA shall also inform to Marketing Department regarding change in Artwork & Regulatory Status.

5.11 After change control approval, Procedures / Specifications / Protocols should be updated as recommended by the Pharmacopoeia / Guideline / FDA circulation.

5.12 Records of updation in Pharmacopoeia & Guidelines shall be maintained by QA in format as shown in **Annexure-I**.

6.0 REFERENCES:

Not Applicable

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Pharmacopoeial Amendments & Guidelines Updates Record	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01 Head Corporate Quality Assurance
- Master Copy Corporate Quality Assurance Department

9.0 ABBREVIATIONS:

No.	Number
Dept.	Department
Ltd.	Limited
QA	Quality Assurance
SOP	Standard Operating Procedure
QC	Quality Control

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
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SOP FOR PHARMACOPOEIAL AMENDMENTS AND GUIDELINES UPDATES

ANNEXURE-I
PHARMACOPOEIAL AMENDMENTS & GUIDELINES UPDATES RECORD

Year:

S.No.	Date	Details of Updation	Reference Pharmacopoeia / Guidelines	Change Affected Documents	Document Reference Number	Effective Date	Updated By Sign & Date	Remarks