STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Annual Review of Drug Product Quality (Annual Product Review)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for annual review of quality of all the products manufactured consistently during the year.

2.0 SCOPE:

This procedure is applicable to the quality review of the products manufactured in ……..

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3.0 RESPONSIBILITY:

Incharge -Production, Store, Quality Control & QA

Head - Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 All batches manufactured during the year shall be considered for the review from January to December.

5.2 During the review, following parameters shall be considered:

- Batch Number
- Batch size
- Description
- Uniformity of weight
- Disintegration time
- Dissolution
- Hardness
- Friability
- Assay
- Any other relevant quality attributes
- Yield data at various stages such as blending, compression, coating and packing.
- Any batches rejected, reprocessed, destroyed etc.

- Review of the batches kept on stability such as number of batches kept, packing details and status on quality attributes etc.
- Number of deviations and change control
- Number of OOS generated.
- Details of product recalls
- Details on market complaints, returned products etc.
- Critical batch processing data to be maintained and evaluated.

5.3 QA shall prepare protocol as well as report summary as per review of above parameter and shall prepare trend of annual product review of each product.

5.4 QA shall prepare each set of data, which shall be tabulated and/or graphed in such a fashion as to easily exhibit results, deviation and trend.

5.5 QA shall summarize to include any recommendations or action plans to address concerns or issues noted.

5.6 APR shall be used to evaluate process control status.

5.7 APR shall be prepared for all batches manufactured in a year.

6.0 ABBREVIATI0N(S):

APR : Annual Product Review

OOS : Out of specification

QA : Quality Assurance

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

---Nil---

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9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION