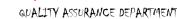
# PHARMA DEVILS





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 .....

#### **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.

# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT



#### STANDARD OPERATING PROCEDURE

STATUTAN OF EXTENSION EVEN			
Department: Quality Assurance	SOP No.:		
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- 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 ABBREVIATION(S):

- APR : Annual Product Review
- OOS : Out of specification
- QA : Quality Assurance

#### 7.0 **REFERENCE**(S):

NA

#### 8.0 ANNEXURE(S):

---Nil----

## PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT



### STANDARD OPERATING PROCEDURE

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### 9.0 **REVISION CARD:**

S.No.	<b>REVISION No.</b>	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION