 Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-018-05	Effective Date:	30.06.2019
	Supersedes:	SOP-QA-018-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	1 of 7
TITLE: ANNUAL PRODUCT QUALITY REVIEW				

1.0 PURPOSE:

To lay down the procedure for the preparation of the Annual Product Quality Review (APQR) and to assess and review the product performance during the review period.

2.0 SCOPE:

This procedure applies to all intermediates and Active Pharmaceutical Ingredients manufactured at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

- 3.1 It is the responsibility of the QA for preparation of APQR.
- 3.2 Head / Designee from QA, QC and Production are responsible to review the APQR.
- 3.3 All concerned department heads have the responsibility to provide relevant data required for the preparation of APQR.
- 3.4 Head-QA /Designee are responsible for the approval of the APQR and for implementation of the recommendations made in the APQR.


4.0 DEFINITIONS:

Nil

5.0 PROCEDURE:

- 5.1 APQR report shall be prepared for the calendar year (January to December) and shall be completed by the end of February of the succeeding year. Any deviations to this calendar shall be addressed through the deviation report.
- 5.2 The APQR shall be prepared by QA in consultation with Production, Quality Control, Warehouse and other departments as applicable.
- 5.3 Separate APQRs shall be prepared for different routes/ processes of same product.

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 Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-018-05	Effective Date:	30.06.2019
	Supersedes:	SOP-QA-018-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	2 of 7
TITLE: ANNUAL PRODUCT QUALITY REVIEW				

5.4 Selection of Batches:

5.4.1 All the batches of starting materials (manufactured / procured), intermediates and Active Pharmaceutical Ingredients (APIs) manufactured during the review period including those reprocessed, rework batches and second crop batches.

5.5 The following details shall be compiled and reviewed in APQR.

5.5.1 Materials:

5.5.1.1 The starting materials are used in the manufacturer of products shall be received from approved vendor and the quality of the material shall be reviewed.

5.5.1.2 The packaging materials are used for final packaging of shall be received from approved vendor and comply with the specifications.

5.5.2 Master Documents:

5.5.2.1 The manufacturing operations shall be performed as per approved batch production record and the document number shall be listed.

5.5.2.2 The analysis of starting materials, in-process, intermediate and API shall be performed as per approved specifications and standard testing procedures and the same shall be reviewed.

5.5.2.3 The packaging operations shall be performed as per approved packaging records and the document number shall be listed.


5.5.3 Manufacturing details:

5.5.3.1 Describe the number of stages consisting of the manufacturing process of Intermediate/ API with document number, block and number of batches produced.

5.5.3.2 Review on critical process parameters in all stages of Intermediate/API.

5.5.3.3 Review of in-process quality parameter for all the stages of Intermediate/ API.

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	Supersedes:	SOP-QA-018-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	3 of 7
TITLE: ANNUAL PRODUCT QUALITY REVIEW				

5.5.3.4 Review on Quality parameter Intermediate/API discrete batches.

5.5.3.5 Review on quality parameter of Intermediate/API, which have been Blended/Micronized/Milled etc. for dispatch.

5.5.3.6 Review on yield of all the stages and Intermediate/API.

5.6 Review of Quality & yield trends:

5.6.1 Review of quality & yield trends of product includes final quality trends of batches of intermediate stages of product, including the batches with assigned cause of variation (OOS, reprocessed and reworked batches), for tests against approved analytical specifications along with graphical representation of trends.

5.6.2 Yield trends of batches of intermediate stages of product, including the batches with assigned cause of variation (OOS, reprocessed and reworked batches), against standard yield along with graphical representation of trends.


5.6.3 Review shall include the derivation of ± 3 sigma limits for quantitative analytical and yield results by considering the batches with normal cause of process variability only. The batches with assigned cause of variation (OOS, OOT, reprocessed and reworked batches) shall not be considered. For deriving these limits, the minimum number of results is 20.

5.6.4 The out control limit batches shall be reviewed / investigated and actions shall be proposed to improve the process / system

5.6.5 Summary & conclusion of review.

5.7 Review of Deviations:

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	Supersedes:	SOP-QA-018-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	4 of 7
TITLE: ANNUAL PRODUCT QUALITY REVIEW				

5.7.1 The deviation raised in all stages for manufacture of Intermediate and API shall be complied with Deviation Report Number, Date of deviation, Description and the corrective and preventive actions.

5.8 Review of Change Controls:

5.8.1 All the changes made to the manufacturing process, equipment, batch production records, specifications, or any other item for API starting materials, Intermediates and APIs shall be summarized.

5.8.2 The review includes Change control Number, description of existing procedure, proposed changes, Category of changes (Major/Minor) along with the status of change controls shall be reviewed and summarized.

5.9 Review of Out of Specifications and Out of trends:

5.9.1 Details of all OOS & OOT results of all stages of the product such as date of reporting, OOS no., product stage code, batch no., description of OOS, actions proposed/ taken, current status of closure along with summary & conclusion.

5.10 Review of Validations:


5.10.1 Details of all validation studies like process, cleaning and analytical method validations related to all the stages of product conducted such as date of protocol approval, validation protocol no., type of validation, reason for validation, current status of study along with summary & conclusion of validation status of respective process.

5.11 Reprocessed & Rework batches:

5.11.1 Reprocessed / Rework batches along with cause and corrective action taken and their final disposition shall be reviewed.

5.12 Hold time data / Stability Study:

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	Supersedes:	SOP-QA-018-04	Next Review Date:	29.06.2022
	Department:	Quality Assurance	Page:	5 of 7
TITLE: ANNUAL PRODUCT QUALITY REVIEW				

5.12.1 Hold time data / Stability data of ongoing batches and the retest period is assigned based on the stability data shall be reviewed.

5.12.2 Capture the batches initiated for hold time / stability during the review period along with the reasons.

5.12.3 Discuss on the trends highlighted with recommended corrective actions, as applicable.

5.12.4 If any hold time / stability batches are discontinued, the reason shall be recorded in the 'Remarks' column.

5.13 Customer Complaints:

Records of complaints shall be reviewed for appropriate closure along with status. The review includes Date of complaint, Complaint number, Customer name, B.NO., Description of complaint shall be reviewed

5.14 Returned Goods:

Records of returned goods shall compiled with details like Date of receipt, Batch No., Customer name, Reason for returned, and the corrective and preventive actions shall be reviewed and summarized.

5.15 Product Recall:


Any recalls during the review period shall be summarized with details of B.No., Customer name, Reason for recall and the status.

5.16 Review on adequacy of CAPA:

The proposed CAPA initiated during the period shall review and summarize with details like CAPA Number, Details and the status.

5.17 Review of last APQR:

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	Department:	Quality Assurance	Page:	6 of 7
TITLE: ANNUAL PRODUCT QUALITY REVIEW				

Any actions recommended in last APQR like previous APQR report approved date, any recommended actions and their status shall be reviewed and summarized.

5.18 Summary Report:

5.18.1 The report shall include discussion on trends for all relevant data supporting the review under summary.

5.18.2 Based on summary of APQR, it shall be concluded by stating whether the process is consistent and in a state of control. Actions arising out of the review shall be concluded with recommendations for CAPA (corrective action and preventive action) including any requalification or revalidation to be taken.

5.18.3 The actionable points shall be documented in the CAPA report. QA shall follow up the recommended CAPA implementation and shall document the completion and the implementation status shall be discussed in the next APQR

5.18.4 The report shall include a conclusion of the Annual Product Quality Review.

5.18.5 If there were no batches manufactured during the period, the APQR shall be prepared with other details like Master Documents, Change controls, validation, Stability data, OOS, Validations, Customer Complaints, Returned goods, Recall and others as applicable (Or) as per customer requirement.

5.19 Retention Time:

The annual product review reports shall be archived at QA documentation area and retain as per the respective SOP.

5.20 Annual product quality review report number shall be follows:


APQR/XXXX/YY

APQR represents : Annual Product Quality Review Report

XXXX represents : Product Code

YY represents : Last two digits of the calendar year

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	Department:	Quality Assurance	Page:	7 of 7
TITLE: ANNUAL PRODUCT QUALITY REVIEW				

e.g.: APQR/DAH/19 Annual Product Quality Review Report for the product DAH during the calendar year 2019.

6.0 FORMATS / ANNEXURE(S):

6.1 Annual Product Quality Review Report : QA018-FM154

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.06.2007	New SOP is introduced.	--
01	01.07.2009	SOP format changed and reviewed for more clarity.	--
02	15.06.2014	Revised as per current SOP & more clear and clarity.	--
03	26.04.2017	1. SOP format changed make to inline with SOP-QA-001-05. 2. Annual product quality review report contents are rephrased and format number allotted. 3. Altogether procedure has been rephrased for better clarity.	CCF/GEN/ 17013
04	30.03.2018	“APQR preparation is not required for less than 10 batches” was removed.	CCF/GEN/ 18006
05	30.06.2019	1. Review procedure for OOS, OOT, Re-process/Rework batches, Validation status, Last year APQR status and previous CAPA verification has been included 2. APQR format revised as per inline to SOP.	CCF/GEN/ 19008

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QA001-FM139-01