POLICY ON ANNUAL PRODUCT QUALITY REVIEW

INTRODUCTION:
This document provides the policy for Annual Product Quality Review to verify the consistency of the existing process to highlight any trends and to identify product and process improvements.

SCOPE:
This policy applies to API and Finished product manufactured at …….... and Associated units.

POLICY DETAILS:

- ✧ There shall be procedure in place for 'Annual Product Quality Review'.
- ✧ Annual Product Quality Review shall be compiled for each product manufactured at site.
- ✧ Product Quality Review shall be carried out on annual or rolling basis and schedule shall be available for the same.
- ✧ 'Annual Product Quality Review' document shall include (but not limited to): A review of starting and packaging materials used in the product, especially those from new sources, review of critical quality Attributes (CQA), critical process controls of finished products, batches that failed to meet established specification and their investigation, all significant non-conformance, change control, marketing authorization variations and post marketing commitment, stability monitoring and any adverse trend, quality related to return, complaints, recalls, qualification status of equipment and utilities, contractual agreements, microbiological trend and status of action taken from previous APQR.
- ✧ Trending and statistical evaluation of data shall be done during review. A minimum of 15 batches data shall be necessary to perform statistical evaluation. Data of previous years (maximum three years) shall be used in case 15 data points are not available.
- ✧ The manufacturer and marketing authorization holder of formulation shall evaluate the results of the review.

Conclusion shall be drawn at the end of review. Need for improvement, if any shall be specified in the conclusion. Any recommendations for revalidation shall also be included in summary conclusion.

Significant outcome of Product Quality Review shall be presented in Quality Management Review.

AMENDMENT AND WAIVER:
The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not Applicable.

ABBREVIATIONS:

API	:	Active Pharmaceutical Ingredient
APQR	:	Annual Product Quality Review
ICH	:	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
WHO TRS	:	World Health Organisation Technical Report Series.

REFERENCES:

WHO TRS 961
Eudralex Volume 4, Chapter 1, Pharmaceutical Quality System ICH Q7