📢 **Get 1 SOP for just ₹299!** *(Instead of ₹500)*
💊 Yes—you read that right!

ANNUAL PRODUCT QUALITY REVIEW (APQR)

DEFINITIONS

Annual Product Quality Review is a regular periodic or rolling quality reviews of all commercial medicinal products which are conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for starting materials, in-process and finished product to monitor trends and to identify product and process improvements, if any

CONTENT

- Product information:
- Summary of Batches Manufactured
- Review of manufacturing process data
  - Critical Process Parameters & Yields
- Review of Analytical Data
  - Review of In-Process & Intermediate Test Results
- Review of Finished Product test results
- Review of Batch Rejections

CONTENT

- Review of Out of Specifications/ Out of Trend results
- Review of Deviations
- Review of Reprocessed/ Reworked Batches/ Repacking
- Review of Change Controls
- Review of Batch Rejections Review of CAPAs (Corrective and Preventive Actions)
- Review of Recalls, Returns, Retention sample

CONTENT

- Review of Stability data
- Review of Validation/ Qualification Status
- Review of Environmental Monitoring
- Review of Water monitoring results
- Review of Utilities
- Review of Post Marketing commitments

CONTENT

- Review of key raw materials & Primary Packaging materials
- Review of Validation/ Qualification Status
- Review of Technical Agreements
- Review of the status against previous APQR recommendations
- Summary and Conclusions
- Recommendations.
- Abbreviations

Referance Guidlines

- Good Manufacturing Practices issued by World Health Organization
- Rules and Guidance for Pharmaceutical Manufacturers and Distributors, year 2007 issued by MHRA
- ICH Q7 - Good Manufacturing Practice Guide for API.

Any questions?

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