STANDARD OPERATING PROCEDURES

REVIEW & AUDITING THE PQ BATCH

1. PURPOSE

The purpose of this Standard Operating Procedure is to provide a procedure for the review and auditing of the process qualification batch.

It is a full simulation of the pivotal process with completed process documentation and fully validated analytical methods, including stability indicating assay analysis.

The intention is to challenge every aspect of the formula, process instructions and *all* product specifications, which include accelerated stability tests of each strength.

2. RESPONSIBILITY

① Symbol indicates work is accepted by Project Manager / Leader /Supervisor.
⑦ Symbol indicates approval and acceptance of the test data, by Quality Assurance.
⑧ Symbol indicates work is accepted by Development Project Manager.

3. FREQUENCY

Following the manufacture of the PQ batch

4. PROCEDURE

Check that the final edition of the analytical documentation (assay, impurities, content uniformity and dissolution tests) have been printed and audited and are test are authorized and signed off.

Manufacture the PQ batch in the plant's commercial facilities where the marketing lots *will be* produced, using standard production raw materials and personnel, as well as routine QA procedures.

Use the full length written manufacturing process instructions and product specific SOPs

Insure the processing equipment used is the same models and operate on the same principle as scheduled for the commercial validation and marketing lots.

Insure that the cleaning procedures and the production SOPs are the same as scheduled for the commercial validation and marketing lots..

REVIEW & AUDITING THE PQ BATCH

Review the PQ Batch documentation under the following headings:-

[4.1]. Active ingredients specifications from ‘approved suppliers'

[4.2]. PQ product formulation.

[4.3]. PQ processing instructions.

[4.4]. PQ in-process specifications.

[4.5]. PQ release specifications.

[4.6]. PQ stability specifications.

[4.7]. PQ F P specifications.

[4.8]. PQ filling specifications.

[4.9]. PQ packaging specifications.

[4.10]. Full analytical S.I. methodology and validation.

[4.11]. Full microbiological methodology and validation.

[4.12]. Full cleaning procedure and cleaning validation.

5. DOCUMENTATION

PQ batch analytical documentation

PQ batch production documentation

[End of Document]

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1. The Process Qualification batch is equal to the 70% or more of the pivotal batch or the smallest commercial batch size that will be validated?	Yes No
2. The active material source has been verified as an 'Approved Supplier' ?	Yes No
3. All non actives are routine production excipients or have been approved.	Yes No
4. The container closure-system is the final marketing pack?	Yes No
5. The Master Product Formula Record has all authorization signatures ?	Yes No
6. The Master Manufacturing Batch Instructions has all authorization signatures?	Yes No
7. The manufacturing flow chart (identifying all equipment and process parameters) is final with all authorization signatures?	Yes No
8. In-process QC specifications and processing parameters are complete?	Yes No
9. Standard packaging instruction (including sampling protocol) complete?	Yes No
10. Release Specifications (with narrower lower and upper limits) complete?	Yes No
11. Check Specifications (with maximum lower and upper limits) complete?	Yes No
12. Overall Finished Product Specifications complete?	Yes No
13. Accelerated stability protocols are complete and signed-off ?	Yes No
14. The analytical methods and stability indicating assay are complete?	Yes No
15. The PQ is not a regulatory requirement but a in-house dry run!	Yes No
16. The Granulate Content Uniformity Protocol is prepared for evaluation during PQ batch manufacture (for tablets & capsules only).	Yes No
17. The Tablet Hardness Qualification protocol will be evaluated during the PQ batch manufacture (for tablets only).	Yes No