PRODUCT DEVELOPMENT FLOWCHART

STAGE 1
LITERATURE SEARCH

STAGE 2
ACTIVE SOURCING

Do not evaluate material while still in a R&D stage.
USE ONLY PRODUCTION ACTIVES

APPROVE a minimum of TWO SUPPLIERS

STAGE 3
ACTIVE EVALUATION

Q3A Impurities cf. innovator's profile

STAGE 4
ACTIVE PURCHASING

STAGE 5
Active testing

STAGE 6
Innovator Product Purchasing

STAGE 7
Innovator Product Testing

STAGE 8
Bulk Active Testing

Purchase a new lot number every 3 months from the smallest to the largest pack size (in each dosage strength)

Q3C - Residual Solvents Check

STAGE 9
Excipient Evaluation

STAGE 10
Container Closure System Choices

STAGE 11
Manufacturing Process Evaluation

STAGE 12
Bulk Active Purchase

DRUG DEVELOPMENT 21 STAGES
PRODUCT DEVELOPMENT

FLOWCHART

Solids Dosage Forms

STAGE 13
Analytical Evaluation

STAGE 14
Process Optimization
PO Batch

STAGE 15.
SCALE-UP

STAGE 16
PROCESS QUALIFICATION

STAGE 17
PIVOTAL BATCH PRODUCTION

STAGE 18
ANDA PRE-SUBMISSION AUDIT

STAGE 19
ANDA SUBMISSION

19B
PRODUCT DEVELOPMENT REPORT

STAGE 20
Process Validation & Statistics
(3 commercial lots)

STAGE 21
Process Revalidation after a major change
(Check SUPAC)

Prepare full Written Protocols for PO Scale-Up & PQ Batches (Future Q6A Requirements will impact on this development)

Review all raw data Development & Lab Notebooks Evaluate all interim reports that form part of the Product Development Report

Process validation lots signify the first THREE consecutive production lots. (Same Batch Size and Active Lot No.)