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| **Sr. No.** | **Change in**  **(Item)** | **Impact On**  **(Due to change in item)** | **Supportive Data / Justification Required** |
| 1 | Mfg. Formula / Components and composition | * Batch mfg. Record * Training * Stability Studies/Shelf life * Label claim of printed PM * Regulatory approval * Product permission * Process validation * Partial analytical method validation (e.g. In case of change in colour of tab, placebo interference should be checked) * FP specification & ATP. * In process specification & ATP * Stability protocol * Bill of Raw Material * Revision of FO/MI * Cleaning validation * Customer approval * Change of MBR,PBR,PI,MI | * In process & FP analytical trend * Supportive data received from SPARC / FDD * Scientific rationale |
| 2 | Manufacturing Site | * Batch mfg. record * Analytical documents * Training * Process validation | * Same working principle of machines/equipment * Equipment Qualification * Scientific rational. * Equipment equivalence |
| 3 | Batch size | * Batch mfg. record * Training * Process validation * Bill of Raw Material * Regulatory approval * Revision of MF and MI or PI or MPR * Equipment design and qualification status | * In process & FP analytical trend. |
| 4 | Critical manufacturing equipment/ | * Batch mfg. Record * Training * Equipment equivalence (operating principle, design, operating parameters, mfg. capacity), impact on product | * Calibration of the equipment. * Equipment Qualification * Equipment equivalence |
| 5 | Cleaning Procedure | * Cleaning validation | * Cleaning validation/   Verification protocol |
| **Sr. No.** | **Change in**  **(Item)** | **Impact On**  **(Due to change in item)** | **Supportive Data / Justification Required** |
| 6 | Mfg. procedure | * Batch mfg. record. * Training * Stability Studies/Shelf life. | * In process & FP analytical Trend * Supportive data received   from SPARC/FDD |
| 7 | Instrument / machine | * Standard Operating Procedure (SOP). * Training to the chemist/analyst.   Master BMR/ Analytical documents | * Supportive data to prove no impact on core quality. |
| 8 | FP Specification | * FP STP * Stability protocol * Training to the analyst * Method validation * FP Template/ LIMS * Batch mfg. record | * Any supportive document received from FDD * FP analytical trend / historical data * Change in pharmacopoeial limit / method. * Comparative data study |
| 9 | Test method | * ATP (Analytical test procedure) * Training to Analyst * Impact on available lots/batches * Analytical method validation * Analytical Tech Transfer | * Supportive data from FDD * Any pharmacopoeial   reference   * Comparative study data |
| 10 | Stability protocol | * Stability specification * Stability analytical test procedure * Training to analyst | * Any supportive document received from FDD. * Change in Pharmacopoeial   limit / method. |
| 11 | RM specification. | * RM standard test procedure. * Raw material inventory system. * RM directory/sample justification sheet. * BMR and BOM * Label claim of printed packing material, if applicable. * Training to the analyst. * Method validation * RM Template/ PLIMS | * RM analytical trend. * Any supportive document received from FDD * Change in pharmacopoeial   limit   * Comparative data study * RM analytical trend/   historical data. |
| **Sr. No.** | **Change in**  **(Item)** | **Impact On**  **(Due to change in item)** | **Supportive Data / Justification Required** |
| 12 | In the process specification/ control specification | * In process analytical test procedure. * Batch mfg. record. * Training to the analyst. * Process Validation * Cleaning Validation * Stability studies * Regulatory approval * Revision of specification * Customer approval * Impact on controlling/monitoring instrument | * In process analytical trend * Any supportive document received from FDD * Comparative study data |
| 13 | Secondary  (printed/ un-printed) packaging material. | * Batch packing record. * Packing material specification and ATP * Pack profile * Training to the analyst * Packaging material inventory system. | * Copy of revised artwork of printed pkg. material. * Justification for the change. |
| 14 | Shelf Life | * Master BMR * Stability study/ Stability protocol * Change in specification * Customer Approval * Regulatory approval or effect Specification (material sampling & handling sheet) | * Supportive data from FDD * Supportive stability study |
| 15 | RM Source / Supplier | * Stability Study ( if active ) * Stability protocol Vendor approval Regulatory effect * API Specification and ATPs * Inclusion of vendor in approved vendor list * Process Validation * Vendor Qualification * Method Transfer , if required | * Comparative study between different RM lot Comparative study of finished product manufactured from these RM |
| 16 | Any standard formats / System. | * Standard Operating Procedure   (SOP). Training to the analyst. | * Any audit comment. * Reference of any incidence report Supportive trend / literature. |
| **Sr. No.** | **Change in**  **(Item)** | **Impact On**  **(Due to change in item)** | **Supportive Data / Justification Required** |
| 17 | Change in item code of API/ Excipient /  Intermediate/  Raw material | * All products BMR/BOM in which material is used. * ERP * Spec/ATP/Stability protocol * Package insert/label/foil * Process validation protocol * Vendor Qualification * Identification of affected stock for HOLD * Identification of affected stock for Rejection * Regulatory approval * Revision of finished product specification * Revision of raw material specification * Revision of FO/MI packing material | * Supportive data to prove no impact on FP quality. |
| 18 | Inclusion of  new pack size | * Revision of stability protocol. * Stability study. * Process validation. * NDC code inclusion in PI or   revision of PI.   * Packing order. * Revision or of pack style. * Processing of Artwork * PO/PI Preparation | * Marketing requirement |
| 19 | Change in Tablet Description:  Addition /deletion of break line / quarter line Change in embossing / debossing  Change in shape of break line (fish shape /straight line) | * Trail to break the tablets.   One batch Dissolution /CU of half tablet – One time study, Friability, Package insert, Stability protocol.  BMR, Process validation protocol. (exhibit/stability)  Reporting category as per SUPAC and MAPP.  Information to FDA. | * FDD recommendation |
| **Sr. No.** | **Change in**  **(Item)** | **Impact On**  **(Due to change in item)** | **Supportive Data / Justification Required** |
| 20 | Inclusion or  deletion of  pack size or  count per bottle. | * Package insert (NDC code). * Packing order. * Pack style. | * Marketing requirement. |
| 21 | Existing Product/  Equipment/  Discontinuation | * Cleaning validation for worst case identification/MACO calculations * Rejection of raw material/packing material stock or transfer to other location * Decision for continuation of   stability study   * Updation of Product planning * To cancel the order of raw   materials/packing materials   * Update of cleaning validation matrix * Retrieval of Operational copies of FO/MI, PO/PI * Retrieval of Operational copies of SOP * Update calibration calendar, PM calendar, RQ Calendar, Inventory List | * Product discontinuation instruction details |
| 22 | Site Transfer | * Availability of identical equipment * VMP/Facility Qualification/Equipment/Critical Utility Qualification * Whether batch size has been changed * Process validation * Cleaning Validation * Analytical method transfer/Mfg. Tech Transfer * Stability Study * MF/MBR revision * Availability of manufacturing license * Approval by regulatory * Resource adequacy in terms of manpower and infrastructure | * Product information |
| **Sr. No.** | **Change in**  **(Item)** | **Impact On**  **(Due to change in item)** | **Supportive Data / Justification Required** |
| 23 | New Product | * Vendor Qualification * Availability of regulatory approval * Stability study * Inclusion of vendor in approved vendor list * Approval of MF and MI (Manufacturing Instructions) * Approval PO (Packaging Order) and ( PI (Packaging Instruction) * Process validation * Availability of scale-up report * Availability of test batch/exhibit batch monitoring report * Cleaning Validation * Resource adequacy in terns of human resources and infrastructure requirements * Impact on contamination/containment issues * Analytical test method development verification/validation | * Product details |
| 24 | New equipment | * Identical equipment * Design qualification * Installation qualification * Utilities requirements * Operational qualification * Performance qualification * Operation and cleaning SOP * Cleaning validation * Process validation * Revision of MI/PI * Preventive Maintenance SOP * Calibration of SOP * Stability Studies * Equipment equivalence * Regulatory approval * Update in equipment inventory /RQ (Re-qualification) Calendar * Update in calibration calendar * Update in preventive maintenance calendar | * Equipment qualification |
| **Sr. No.** | **Change in**  **(Item)** | **Impact On**  **(Due to change in item)** | **Supportive Data / Justification Required** |
|  |  | * Equipment Log * Sterilization SOP * Update Equipment Layout * Update Validation matrix (VMP) * Microbiology (E. g. Media fill, EM) * Special Training * Specialized resources * Revision to as built engineering diagrams |  |
| 25 | Change in Equipment | * Utilities requirements * Cleaning validation * Process validation * Revision of MI/PI * Stability Studies * Equipment equivalence * Regulatory approval * Update in equipment inventory /RQ (Re-qualification) Calendar * Update in calibration calendar * Update in preventive maintenance calendar * Equipment Log/ History record * Supplementary qualification or IQ/OQ/PQ | * Change in facility. |
| 26 | Change in Layout/Facility | * Is there a change in layout * Environment control as per specialization (HVAC) * Area qualification/ Re-qualification * Contamination/cross contamination * Special training * Impact on available resources * Approval of regulatory agency * Revision to as built engineering diagrams | * Changes in Site master file |
| 27 | Change in utility equipment | * Supplementary qualification or IQ/OQ /PQ * Revision of SOP * Revision of MI/PI * Revision of PM SOP * Update in equipment inventory/RQ calendar | * Change in utility equipment |
| **Sr. No.** | **Change in**  **(Item)** | **Impact On**  **(Due to change in item)** | **Supportive Data / Justification Required** |
|  |  | * Update in calibration calendar * Update in preventive maintenance calendar * Revision to as-built engineering diagrams |  |
| 28 | Change in art work/Packaging material/Labelling change | * Revision of PO/PI * Revision of art work * Revision of packaging specification * Regulatory approval * Identification of affected stock for HOLD and Blocking of existing code for further ordering * Destruction of negative/plates at vendor end * Marketing approval * Identification of affected stocks for Rejection | * Art work |
| 29 | Change in Vendor | * API specs and STPs * Method transfer, if required * Vendor Qualification * Inclusion of vendor in approved vendor list * Stability study * Regulatory approval available * Process validation * Revision of FO/MI, or PO/PI | * Vendor qualification |
| 30 | Change in Document (Specification/  STP/ SOP/  Protocol | * Document revision * Regulatory approval * Training | * System implementation |
| 31 | Regulatory agency | * Any requirement of regulatory agency | * Regulatory requirement |
| 32 | Personal and General Issues | * Customer requirement * Marketing requirement | * Requirement |
| 33 | GxP Computer system | * Change in GxP category 3, 4, 5 computer systems, Revision of SOP * Change in infrastructure components * Supplementary qualification or IQ/OQ/PQ | * Computer system qualification |