



| Current Good Manufacturing Practices for Finished Pharmaceuticals Services Action Items | | | | |
|---|--|--|-------------------------|--|
| Services | Areas | Programs/Policies/Procedures/Forms/ Lessons | Action Items | |
| All Inclusive – customized to the Code of Federal Regulations | Subpart A - General Provisions | Current Good Manufacturing Practice for | Collect/Provide Records | |
| | -Scope: 1. Inclusion: Current Good Manufacturing Practice to Drug | Finished Pharmaceuticals | Assess | |
| | Products for administration to humans or animals | | Develop | |
| | 1a. Biological products for human use | | Review | |
| | 1b. Human cells, tissues, and cellular and tissue-based | | Approve | |
| | products (HCT/Ps) | | Implement | |
| | Subpart B - Organization and Personnel - Program (Documentation of training, including the date of the training, the type of training, and the person(s) trained) -Responsibilities of quality control unit -Personnel qualifications -Personnel responsibilities -Consultants | Management Responsibility | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Personnel Qualification | Collect/Provide Records | |
| | | 1 craoriner Qualification | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Training | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Job Description | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify Validate | |
| Cubant C. Buildings | Subport C. Buildings and Excilities Brogram | Premises Location | Collect/Provide Records | |
| | Subpart C - Buildings and Facilities - Program -Design and construction features -Lighting -Ventilation, air filtration, air heating and cooling -Plumbing -Sewage and refuse -Washing and toilet facilities -Sanitation -Maintenance | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Grounds and Roadways | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Cleaning and Sanitation | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |





| Currer | t Good Manufacturing Practices for Finishe | | | |
|----------|--|--|-------------------------|--|
| Services | Areas | Programs/Policies/Procedures/Forms Lessons | Action Items | |
| | | | Validate | |
| | | Sanitation Standard Operating | Collect/Provide Records | |
| | | Procedures | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Building Materials | Collect/Provide Records | |
| | | 3 | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Lighting and Light Fittings | Collect/Provide Records | |
| | | Lighting and Light Fittings | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Ventilation | Collect/Provide Records | |
| | | ventilation | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | | |
| | | | Approve Implement | |
| | | | | |
| | | | Verify Validate | |
| | | Denoise and Maintenance | | |
| | | Repairs and Maintenance | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | 0.1 10.5 1.0 | | Validate | |
| | Subpart D - Equipment Program | Equipment - Maintenance | Collect/Provide Records | |
| | -Equipment design, size, and location -Equipment construction | | Assess | |
| | -Equipment cleaning and maintenance | | Develop | |
| | -Automatic, mechanical, and electronic equipment | | Review | |
| | -Filters | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Equipment - Calibration | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Equipment - Cleaning and Sanitation | Collect/Provide Records | |
| | | | Assess | |
| | | | | |
| | | | Develop | |





| | | Programs/Policies/Procedures/Forms/ | |
|----------|--|--|------------------------|
| Services | Areas | Lessons | Action Items |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | Capitation Standard Operating | |
| | | Sanitation Standard Operating Procedures | Collect/Provide Record |
| | | Troccaires | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | Subpart E - Control of Components and Drug Product | Receipt, Storage and Handling | Collect/Provide Record |
| | Containers and Closures - Program | Treespi, eterage and rianamig | Assess |
| | -Receipt and storage of untested components, drug product | | Develop |
| | containers, and closures | | · · |
| | -Testing and approval or rejection of components, drug product | | Review |
| | containers, and closures -Use of approved components, drug product containers, and | | Approve |
| | closures | | Implement |
| | -Retesting of approved components, drug product containers, | | Verify |
| | and closures | | Validate |
| | -Rejected components, drug product containers, and closures | Receiving Log | Collect/Provide Record |
| | -Drug product containers and closures | | Assess |
| | | | Develop |
| | | | Review |
| | | | |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | Receiving Protocol | Collect/Provide Record |
| | | | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | - |
| | | | Verify |
| | | | Validate |
| | | Non Conforming Materials and Products | Collect/Provide Record |
| | | | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | Draduat Dalagae Maniferina | |
| | | Product Release Monitoring | Collect/Provide Record |
| | | | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | Loading, Transport and Unloading | Collect/Provide Record |
| | | Practices | |
| | | | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | I . | | Verify |
| | | | verny |
| | | | Validate |





| -Written procedures; deviations -Charge-in of components -Calculation of yield -Equipment identification -Sampling and testing of in-process materials a | Programs/Policies/Procedures/Forms/ Lessons | Action Items Assess |
|--|---|---------------------------------------|
| -Charge-in of components -Calculation of yield -Equipment identification | | |
| -Calculation of yield -Equipment identification | | |
| -Equipment identification | | Develop |
| | | Review |
| | and drug | |
| products | and drug | Approve |
| -Time limitations on production | | Implement |
| -Control of microbiological contamination | | Verify |
| -Reprocessing | | Validate |
| | Standard Operating Procedures | Collect/Provide Records |
| | | Assess |
| | | Develop |
| | | Review |
| | | Approve |
| | | Implement |
| | | Verify |
| | | <u> </u> |
| | | Validate |
| | Product Formulation and Realization | Collect/Provide Records |
| | | Assess |
| | | Develop |
| | | Review |
| | | Approve |
| | | Implement |
| | | Verify |
| | | Validate |
| | Product Sampling | Collect/Provide Records |
| | Product Sampling | |
| | | Assess |
| | | Develop |
| | | Review |
| | | Approve |
| | | Implement |
| | | Verify |
| | | Validate |
| | Production/Batch Monitoring Report | Collect/Provide Records |
| | i roddollom Baton morntoning riopont | Assess |
| | | Develop |
| | | · · · · · · · · · · · · · · · · · · · |
| | | Review |
| | | Approve |
| | | Implement |
| | | Verify |
| | | Validate |
| | Product Testing Protocol | Collect/Provide Records |
| | | Assess |
| | | Develop |
| | | Review |
| | | |
| | | Approve |
| | | Implement |
| | | Verify |
| | | Validate |
| | Reprocessing Procedure | Collect/Provide Records |
| | | Assess |
| | | Develop |
| | | Review |
| | | Approve |
| | | Implement |
| | | |
| | | Verify |
| | | Validate |
| | Program Specifications - Packaging and Labeling | Collect/Provide Records |
| Subpart G - Packaging and Labeling Control - | | 1. |
| -Materials examination and usage criteria. | Materials | Assess |
| -Materials examination and usage criteriaLabeling issuance. | | Assess Develop |
| -Materials examination and usage criteria. -Labeling issuance. -Packaging and labeling operations. | Materials | Develop |
| -Materials examination and usage criteriaLabeling issuance. | Materials | |





| Curren | t Good Manufacturing Practices for Finished Pl | | | |
|----------|---|--|--|--|
| Services | Areas | Programs/Policies/Procedures/Forms/ Lessons | Action Items | |
| | -Expiration dating. | | Verify Validate | |
| | | Label Verification/Reconciliation | Collect/Provide Records | |
| | | Laber vermeation/recontinuation | Assess | |
| | | | | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | Subpart H - Holding and Distribution - Program | Good Warehousing Procedures/ | Collect/Provide Records | |
| | -Warehousing procedures. | Standard Operating Procedures | Assess | |
| | -Distribution procedures. | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Stock Rotation Procedure | Collect/Provide Records | |
| | | Stock Rotation Procedure | | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | Subpart I - Laboratory Controls - Program | Stability Testing Procedure | Collect/Provide Records | |
| | -Specifications, standards, sampling plans, test procedures, or | | Assess | |
| | other laboratory control mechanisms | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Product Identification - Reserved Sample Procedure | Collect/Provide Records | |
| | | | | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | Laboratory Testing Protocol | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | Subpart I Pacards and Paparts Program | Equipment Cleaning and Use Log | Collect/Provide Records | |
| | Subpart J - Records and Reports - Program -Production, control, and/or distribution records -Production record review | Equipment Cleaning and Use Log | | |
| | | | Assess | |
| | -Production record review | | Develop | |
| | -Production record review | | | |
| | -Production record review | | Review | |
| | -Production record review | | Review Approve | |
| | -Production record review | | Review Approve Implement | |
| | -Production record review | | Review Approve Implement Verify | |
| | -Production record review | | Review Approve Implement | |
| | -Production record review | Inventory - Component, Drug product | Review Approve Implement Verify | |
| | -Production record review | Inventory - Component, Drug product container, Closure, and Labeling forms/records | Review Approve Implement Verify Validate | |





| Current | Good Manufacturing Practices for Finished Pl | harmaceuticals Services Action | Items |
|----------|---|--|---|
| Services | Areas | Programs/Policies/Procedures/Forms/ Lessons | Action Items |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | Master Production and Control | Collect/Provide Records |
| | | forms/records | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify Validate |
| | | Laboratory and Testing forms/records | Collect/Provide Records |
| | | Laboratory and resting forms/records | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | Distribution forms/records | Collect/Provide Records |
| | | | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | Complaint forms/records | Collect/Provide Records |
| | | | Assess |
| | | | Develop Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | Subpart K - Returned and Salvaged Drug Products - Program | Returned Drug Products | Collect/Provide Records |
| | -Returned drug products | | Assess |
| | -Drug product salvaging | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | Destroying and or Disposal of Expired, | Collect/Provide Records |
| | | Damaged, Recalled, Rejected Returned and Non-conforming Drug Procedure | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| į. | | | Implement |
| | | | Verify Validate |
| | | | vandate |
| | | Peturned Druge Quality Evaluation | |
| | | Returned Drugs Quality Evaluation Procedure | Collect/Provide Records |
| | | Procedure | Collect/Provide Records Assess |
| | | Procedure | Collect/Provide Records Assess Develop |
| | | Procedure | Collect/Provide Records Assess Develop Review |
| | | Procedure | Collect/Provide Records Assess Develop Review Approve |
| | | Procedure | Collect/Provide Records Assess Develop Review |





| Current Good Manufacturing Practices for Finished Pharmaceuticals Services Action Items | | | | |
|---|--|--|-------------------------|--|
| Services | Areas | Programs/Policies/Procedures/Forms/ Lessons | Action Items | |
| | 21 CFR 111 Dietary Suppleme | ent cGMP (Storage and Distribution) | Services | |
| Inclusive – customized to the | Subpart M - Holding and Distributing | Receipt, Storage and Handling of Goods | Collect/Provide Records | |
| le of Federal Regulations | - Holding Conditions Program | 3 | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | | Verify | |
| | | | Validate | |
| | | Corrective and Preventative Action | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | | Verify | |
| | | | | |
| | | | Validate | |
| | Subpart M - Holding and Distributing Program | Product Sampling | Collect/Provide Records | |
| | - Reserved Samples Procedure | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | | Verify | |
| | | | Validate | |
| | | Non Conformina Materials and Bradusts | | |
| | | Non Conforming Materials and Products | Collect/Provide Records | |
| | | | Assess | |
| | | | Develop | |
| | Subpart M - Holding and Distributing - Distribution Conditions Program | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | | Verify | |
| | | | Validate | |
| | | Loading Transport and Unloading | | |
| | | Loading, Transport and Unloading Practices | Collect/Provide Records | |
| | | . 1400000 | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | Implement | |
| | | | Verify | |
| | | | Validate | |
| | | | Verify | |
| | | | Validate | |
| | Subpart P - Records and Recordkeeping Program | Label Artwork/Reference | Collect/Provide Records | |
| | Support 1 - Necolus and Necolukeeping Flogram | Laber Artwork Nacionalice | | |
| | | | Assess | |
| | | | Develop | |
| | | | Review | |
| | | | Approve | |
| | | | | |
| | | | Implement | |
| | | | | |
| | | | Implement | |
| | | | Implement Verify | |





| | | Programs/Policies/Procedures/Forms | |
|----------|-------|------------------------------------|-------------------------|
| Services | Areas | Lessons | Action Items |
| | | Shipping Records | Collect/Provide Records |
| | | | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | | Verify |
| | | | Validate |
| | | Distribution Records | Collect/Provide Records |
| | | | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | | Verify |
| | | | Validate |
| | | Import Documentation | Collect/Provide Records |
| | | | Assess |
| | | | Develop |
| | | | Review |
| | | | Approve |
| | | | Implement |
| | | | Verify |
| | | | Validate |
| | | | Verify |
| | | | Validate |

FR 20241007