GMP Audit Checklist

Check if all the points under each component are compliant.
Apply corrective actions in case of non-compliance.

☐ Quality Management System (QMS)

- ☐ Is the QMS documented and up to date?
- ☐ Are procedures followed to maintain the QMS?
- ☐ Is there a system in place to handle and document non-conformances?

☐ Personnel

- ☐ Are personnel trained and qualified for their roles?
- ☐ Are personnel following hygiene and safety procedures?
- ☐ Are personnel records up to date and accurate?

☐ Facilities and Equipment

- ☐ Are facilities and equipment clean and well-maintained?
- ☐ Are equipment calibration and validation records up to date?
- ☐ Are facilities and equipment designed to prevent contamination and cross-contamination?

☐ Materials Control

- ☐ Is there a system in place to ensure the quality of incoming materials?
- ☐ Are materials stored in appropriate conditions?
- ☐ Are materials tracked and labeled accurately?

☐ Production Operations

- ☐ Are production processes documented and followed consistently?
- ☐ Is there a system in place to track production batches and materials used?
- ☐ Are there procedures to prevent contamination and cross-contamination during production?

☐ Packaging and Labeling

- ☐ Are packaging and labeling procedures documented and followed consistently?
- ☐ Are labels accurate and complete?
- ☐ Is there a system in place to track and control packaging materials?

☐ Quality Control

- ☐ Is there a system in place to test finished products for quality and safety?
- ☐ Are testing procedures documented and followed consistently?
- ☐ Are test results recorded accurately and completely?

☐ Documentation

- ☐ Is all GMP-related documentation complete, accurate, and up to date?
- ☐ Is there a system in place to control and maintain GMP-related documentation?
- ☐ Is all documentation accessible and properly stored?

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