FDA GMP Audit Checklist

Quality Control | US

DATE	FACILITY	AUDITOR	AREAS INSPECTED
____ / ____ / _____			

PERSONNEL PRACTICES

	OK	DEFICIENCY
Adequate handwashing observed *§117.10(b) — thorough handwashing*	○	○
Clean outer garments worn	○	○
Hair restraints in use	○	○
No jewelry in processing areas	○	○
Glove use and change practices proper	○	○
Illness reporting policy enforced	○	○
No eating, drinking, or tobacco in plant	○	○
Personal belongings stored away from production	○	○

BUILDINGS & GROUNDS

	OK	DEFICIENCY
Grounds maintained — no harborage *§117.20(a) — pest harborage minimised*	○	○
Adequate drainage around facility	○	○
Walls, floors, ceilings in good repair	○	○
Adequate lighting in all areas	○	○
Light fixtures shielded or shatter-proof	○	○
Ventilation adequate, no condensation	○	○
Handwash stations supplied and accessible	○	○
Restrooms clean, self-closing doors	○	○

EQUIPMENT & UTENSILS

	OK	DEFICIENCY
Food-contact surfaces sanitary design *§117.40 — smooth, non-porous, non-absorbent*	○	○
Equipment clean and in good repair	○	○
No paint peeling or rust on equipment	○	○
Utensils stored in sanitary manner	○	○
Thermometers and measuring devices calibrated	○	○

Compressed air filters in place ☐ OK ☐ Deficiency ☐ N/A

PRODUCTION & PROCESS CONTROLS

	OK	DEFICIENCY
Raw materials inspected on receipt	○	○
Ingredients stored to prevent contamination	○	○
Time and temperature controls followed	○	○
Cross-contamination prevented	○	○
Chemical and cleaning agents segregated	○	○
Product coding and lot traceability	○	○

SANITATION & PEST CONTROL

	OK	DEFICIENCY
Master sanitation schedule followed	○	○
Pre-operational sanitation checks done	○	○
Sanitizer concentrations verified	○	○
Pest control programme active	○	○
No evidence of pest activity	○	○
Waste handled to prevent contamination	○	○

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WAREHOUSING & DISTRIBUTION

	OK	DEFICIENCY		OK	DEFICIENCY
Storage off floor on pallets or racks	○	○	FIFO rotation followed	○	○
Adequate space between stacks and walls	○	○	Returned and rejected product segregated	○	○
Temperature-controlled storage monitored	○	○	Shipping vehicles clean and appropriate	○	○

AUDIT FINDINGS

Critical deficiencies (potential 483 observations)

Minor deficiencies

Corrective actions and deadlines

Auditor signature _____

Plant manager signature _____

Notes

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