Quality Assurance (QA) Audit Checklist for Non-Sterile Compounding:

(Based on NAPRA MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-STERILE PREPARATIONS and Guidance Document)

Pharmacy Name: _____

Date of Audit: _____

Auditor(s): _____

Section 1: Personnel Training and Competency

Item	Verification	Findings	Corrective Action (if needed)
Initial training completed for all compounding staff	Yes / No -		
Annual competency assessments completed	Yes / No -		
Staff training updated after SOP revisions	Yes / No -		
Training records available and complete	Yes / No -		

Section 2: Facilities and Equipment Maintenance

Item	Verification	Findings	Corrective Action (if needed)
Compounding area designated and maintained	Yes / No -		
Cleaning logs up to date	Yes / No -		
Equipment properly maintained and calibrated	Yes / No -		
Environmental controls (ventilation, temperature) adequate	Yes / No -		

Section 3: Compounding Process and Product Quality Control

Item	Verification	Findings	Corrective Action (ifneeded)
Compounding records completed for each preparation	Yes / No -		
Master Formulation Records available and accurate	Yes / No -		
Labeling meets standards (active ingredients, BUD, storage)	Yes / No -		
Physical inspection (e.g., uniformity, absence of contamination) completed	Yes / No -		
Specific QC tests performed as applicable (e.g., pH, weight checks)	Yes / No -		

Section 4: Risk Assessment and PPE

Item	Verification	Findings	Corrective Action (if needed)
Risk assessments documented for each preparation	Yes / No -		
PPE used appropriately according to risk level	Yes / No -		
PPE training records available	Yes / No -		

Section 5: Incident Reporting and Policy Compliance

Item	Verification	Findings	Corrective Action (if needed)
Incident and deviation logs maintained	Yes / No -		
Corrective actions documented and completed	Yes / No -		
Policies and procedures reviewed within last 3 years	Yes / No -		
Staff acknowledgment of policies documented	Yes / No -		

Section 6: Recall Procedures

Item	Verification	Findings	Corrective Action (if needed)
Recall procedure established and documented	Yes / No -		
Recall drills or mock exercises completed	Yes / No -		

Summary of Audit

Area	Overall Compliance (Choose One)	Notes
Personnel Training	Compliant / Partially Compliant / Non-Compliant -	
Facility & Equipment	Compliant / Partially Compliant / Non-Compliant -	
Process & Product Quality	Compliant / Partially Compliant / Non-Compliant -	
Risk Management & PPE	Compliant / Partially Compliant / Non-Compliant -	
Incident Reporting & Policies	Compliant / Partially Compliant / Non-Compliant -	
Recall Procedures	Compliant / Partially Compliant / Non-Compliant -	

Overall Audit Result: _____

Follow-up Date (if needed): _____

Signature of Auditor(s): _____