Standards for Pharmacy Compounding of Non-sterile Preparations Information Sheet

Implementation Deadlines

Phase one	In effect
Phase two	In effect
Phase three	In effect
Phase four	April 1, 2021

Important Resources

Where do I start? Guidance Document

NAPRA Guidance Document

Non-Sterile Compounding Pharmacy Quality Assurance Self-Assessment

Please note: The above Quality Assurance Self-Assessment is a tool for gap analysis and should not be submitted to the College for approval or review.

Decision Algorithm for Risk Assessment

The following phases are outlined in the NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations

Phase one

Section 4 - Assessing risk for compounding non-sterile preparations

Section 5 - Requirements for all levels of non-sterile compounding activities

Section 6.5 - Conduct of personnel

Section 8.1 - Level A requirements

Phase two

Section 6.1 - BUD and dating methods

Section 6.2 - Master formulation record

Section 6.3 - Ingredients used for compounding

Section 6.4 - Compounding record

Phase three

Section 6.6 - Verification

Section 6.7 - Labeling and packaging

Section 6.8 - Storage

Section 6.9 - Transport and delivery

Section 6.10 - Product recalls

Section 6.11 - Incidents and accidents

Section 7 - Quality Assurance

Section 8.2 - Level B requirements

Phase four

Section 9 - Requirements for hazardous preparation

Section 8.3 - Level C requirements