OFFICIAL PUBLICATIONS

Nonsterile Compounding: Guidelines for Healthcare Facility Pharmacies (1992)

Canadian Society of Hospital Pharmacists
Société canadienne des pharmaciens d'hôpitaux

Nonsterile Compounding: Guidelines for Healthcare Facility Pharmacies

Published by the Canadian Society of Hospital Pharmacists (CSHP), Ottawa, Ontario. 1992 edition. Use of this document was approved by CSHP Council in 1992.

Suggested citation:

Canadian Society of Hospital Pharmacists. Nonsterile compounding: guidelines for healthcare facility pharmacies. Ottawa (ON): Canadian Society of Hospital Pharmacists; 1992.

© Canadian Society of Hospital Pharmacists 1992

Nonsterile Compounding: Guidelines for Healthcare Facility Pharmacies

PREFACE

This is the 1992 edition of the Canadian Society of Hospital Pharmacists Nonsterile Compounding: Guidelines for Healthcare Facility Pharmacies. It is one of a series of documents establishing criteria for the practice of pharmacy in hospitals.

These Guidelines were developed to assist hospital pharmacists to assess current practices in bulk compounding and to develop appropriate procedures and controls relative to bulk compounding.

Bulk compounding is an integral part of hospital pharmacy practice. (See CSHP Standards of Practice.) Often the institution's goals and scope of medical staff practices require pharmacy's participation in research as well as in the development of unique dosage forms. This capability in pharmacy facilitates optimum medical management of patients.

These guidelines were approved under the title of Guidelines for Bulk Compounding of Products in Hospitals; the title was fine-tuned in 2009.

1. SCOPE

1.1

These Guidelines set forth procedures and controls to assist in assuring the quality of a bulk compound product.

1.2

These Guidelines are intended to include all nonsterile and sterile products prepared from raw materials. (Intravenous products prepared from commercially available injectable products are excluded). Sterile injectable products should also comply with the Intravenous Therapy Guidelines (see Bibliography).

1.3

These Guidelines were intended to augment but not replace the hospital's existing policies and procedures relative to bulk compounding.

2. GLOSSARY OF TERMS, ABBREVIATIONS, AND SYMBOLS

The following definitions apply for terms used in these guidelines. They may have different meanings in other contexts.

Bulk compounding	The preparation of products which are not commercially available, in anticipation of a physician's order.
Commercially available (product)	A pharmaceutical product authorized for use in Canada by the Health Protection Branch, Health and Welfare Canada, and having received Notice of Compliance, has been assigned a Drug Identification Number (DIN) and marketed in Canada.
Master Formula	Set of instructions outlining in detail the materials, equipment, and procedures required to produce a specific quantity of a product.
WHMIS (Workplace Hazardous Materials Information Systems)	Federal and provincial legislation to ensure information regarding hazards of materials used in workplaces is provided to employers and employees.

3. PERSONNEL

All bulk compounding should be conducted under the supervision of a pharmacist who possesses the knowledge, experience and ability to assume the responsibility for same. All personnel handling materials affected by the WHMIS legislation should receive the proper training.

4. PREMISES

The area designated for bulk compounding should:

a) be sanitary;
b) permit effective cleaning of all surfaces;
c) minimize the potential for contamination of the drug;
d) minimize the potential for the addition of any extraneous material; and
e) be conducive to the orderly flow of work.

5. EQUIPMENT

5.1

The equipment used in bulk compounding should:

a) permit effective cleaning;
b) minimize the potential for contamination of the product;
c) minimize the potential for the addition of extraneous material to the product;
d) be operated only for its intended use;
e) be subject to preventative maintenance procedures; and
f) be checked periodically for proper functioning and calibration.

5.2

Policies and procedures related to the use and maintenance of such equipment should be in accordance with the hospital's policies and procedures pertaining to occupational health and safety.

6. BULK COMPOUNDING CONTROL

6.1 Procedures

6.1.1

Written procedures should be in place for each bulk compounded product to ensure that the end product will meet the specifications for that product. A pharmacists shall assume responsibility for the final product and carry out appropriate checks at critical steps in the process.

6.1.2

The hygiene of all personnel participating in bulk compounding should be guided by policy and procedures within the department as well as the hospital employees' health and safety requirements.

6.1.3

Protective apparel may be appropriate to minimize contamination of the product during processing or packaging and to help protect the employee.

6.2 Master Formula

The master formula should indicate:

a) the name of product;
b) the dosage form of the product;
c) the specifications and source of each raw material used;
d) the formulation of each batch stating:
    i) weights and measures of each raw material; and
    ii) theoretical yield;
e) the equipment required;

f) a description of each step in the compounding process with special notations as required (e.g., which steps or measurements must be verified by a pharmacist or a second person);
g) the shelf life, when applicable;
h) the storage requirements;
i) specific packaging requirements;
j) a sample label, including WHMIS and auxiliary labeling where applicable;
k) the quality control testing to be performed, when applicable; and
l) reference sources for the formula, stability data, if available.

6.3 Production Records

6.3.1

A separate production record should be used for each batch compounded.

6.3.2

The production record should include:

a) the date of compounding;
b) the lot or batch number assigned to the compounded product;
c) the manufacturer's name and lot number of each raw material used;
d) a provision for sign-off of each step in the compound for the person compounding and the person checking;
e) the process, including weights and measures performed;
f) the results of all quality control testing;
g) a statement of final yield;
h) signatures for final verification and authorization for release;
i) a sample label; and
j) the expiry date of the product.

6.4 Raw Material

6.4.1

The quality and identity of all raw materials used in bulk compounding should be verified using a certificate of analysis from the chemical supplier or the label claims of commercially available products used in the compounding process.

6.4.2

Specifications should be of pharmacopoeial or equivalent status.

6.5 Labelling

The labelling of the finished product should be permanent and contain descriptive information including:

a) the name of product;
b) the strength of product;
c) the dosage form of product;
d) the lot or batch number;
e) storage conditions, when applicable;
g) the expiry date;
h) auxiliary labels; and
i) WHMIS labelling where applicable.

6.6 Packaging

The packaging of the finished product should:

a) be appropriate for the dosage form;
b) protect the product from light and moisture as necessary;
c) minimize the potential for interaction between the drug and the container; and
d) be sterile and free from particulate matter for sterile products.

6.7 Record Keeping

Records should be kept for an appropriate period of time in compliance with hospital procedures.

Note: *The Good Manufacturing Practices for Drug Manufacturers and Importers, Health and Welfare, Canada, suggests a period of one year after the expiration date on the label of the compounded product.*

6.8 Reporting

Hospitals should comply with all reporting regulations required by the Health Protection Branch.

6.9 Quality Control

6.9.1 Premises

Written procedures for cleaning the bulk compounding area should include:

a) the cleaning interval;
b) cleaning agents and their concentrations; and
c) disposal of waste material and debris.

6.9.2 Equipment

Routine equipment maintenance, calibration, and certification should be defined, documented, and carried out.

6.9.3 End Product Testing

6.9.3.1 Nonsterile Products

Appropriate end product testing methods should be performed.

6.9.3.2 Sterile Products

Sterility tests should be performed on bulk compounded sterile products.

7. BIBLIOGRAPHY

Good Manufacturing Practices for Drug Manufacturers and Importers, Health and Welfare Canada, Ottawa, Ontario, 1985.

Intravenous Therapy Guidelines, Health and Welfare Canada, Ottawa, Ontario 1982. Revision expected 1989.

Standards of Practice, Canadian Society of Hospital Pharmacists, Toronto, Ontario, 1986. Revision expected 1990.

WHMIS - see federal Bill - C-70 and provincial legislation on Occupational Health and Safety.