



College of Pharmacists of Manitoba

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Guidelines on sterile production in pharmacies, and handling and disposal of hazardous pharmaceuticals (All areas of practice)

Manitoba has adopted the guidelines of the Canadian Society of Hospital Pharmacists (CSHP) for the preparation of sterile products and the handling and disposal of hazardous products for all areas of pharmacy practice in Manitoba, with the addition of the following statement and appendices:

Pharmacists possess the knowledge and skills to properly prepare sterile compounds. It is crucial that pharmacists understand the risks associated with the preparation of these products and with their limitations in this area. If a pharmacist does not have a good understanding of sterile compounding or if he/she does not possess the appropriate equipment, etc., it is better for the pharmacist to:

- Advise a patient to seek a pharmacy capable of preparing sterile products;
- Contact the prescriber and suggest an alternate product;
- Consult with the local hospital pharmacy, or another pharmacy to evaluate options

Sterile compounding cannot be prepared if products cannot be compounded properly. Pharmacist filling prescriptions for sterile products need to ensure the pharmacy where they are working has the proper equipment and in good working order.

Pharmacists must review their resources to determine if sterile compounding is a service they are able to provide.

Provided that proper technique is used, policies and procedures are followed, and facilities are designed correctly, sterile compounding can be done with minimal risk of contamination in the community pharmacy.

Remember that the onus is ultimately on the pharmacist to ensure the proper preparation of sterile products

Appendix 1: Comparison of Risk Categories;

Appendix 2: Reference List

Appendix 3: Refer to CSHP "Guidelines for Preparation of Sterile Products in Pharmacies;"

Appendix 4: Refer to CSHP "Guidelines for the Handling and Disposal of Hazardous Pharmaceuticals (Including Cytotoxic Drugs)"

Appendix 1:

A Comparison of Risk Categories

<p align="center">USP Section <1206></p>	<p align="center">ASHP Technical Assistance Bulletin</p>
<p>Low Risk Category Sterile drug products transferred from vials or ampoules into sterile final containers with syringe and needle</p> <p>Sterile drug products transferred into sterile elastomeric infusion containers with aid of mechanical pump and appropriate sterile transfer device, with or without subsequent addition of sterile drug products with sterile syringe and needle</p> <p>Sterile nutritional solutions combining dextrose injection and amino acid injection via gravity transfer into sterile empty containers, with or without addition of sterile rugs to final container with sterile syringe and needle</p>	<p>Risk Level 1 Single patient admixtures</p> <p>Single patient ophthalmics with preservatives</p> <p>Single patient syringes without preservatives used in 28 hours</p> <p>Batch prefilled syringes with preservatives</p>
<p>High Risk Category I Sterile nutritional solutions compounded with automated compounder, involving repeated attachment of fluid containers to proximal openings of compounder tubing set and of empty final containers to distal opening</p> <p>Additive transfers into filled final container from individual drug products containers or from pooled additive solution</p> <p>Ambulatory pump reservoirs prepared by adding more than one drug product, with evacuation of air from reservoir prior to dispensing</p> <p>Ambulatory pump reservoirs prepared for multiday (ambient temperature) administration</p>	<p>Risk Level 2 TPNs for administration after 7 days</p> <p>Injections for use in portable pump or reservoir</p> <p>Batch reconstituted antibiotics without preservatives</p> <p>Batch prefilled syringes without preservatives</p>
<p>High Risk Category II Injectable morphine solutions prepared from nonsterile morphine substance and suitable vehicles</p> <p>Sterile nutritional solutions prepared from nonsterile ingredients, with initial mixing in non-sealed or nonsterile reservoir</p>	<p>Risk Level 3 Alum bladder irrigations</p> <p>Morphine injections made from powder or tablets eg for PCA</p> <p>TPN solutions made from dry amino acids</p> <p>Autoclaved IV solutions</p> <p>TPNs sterilized by final filtration</p>

Note: USP section 1206 has been revised and is now Section 797

Appendix 2: Reference List

Appendix 2.1 Reference Sources

1. American Society of Health-System Pharmacy

7272 Wisconsin Avenue Bethesda, MD 20814

Phone: 301-657-3000

Website: www.ashp.org

2. Canadian Pharmacists Association

1785 Alta Vista Drive Ottawa, Ontario K1G 3Y6

Tel: 1-800-917-9489 or (613) 523-7877

Fax: (613) 523-0445 Website: www.pharmacists.ca

3. Canadian Society of Hospital Pharmacists

1145 Hunt Club Road, Suite 350

Ottawa, ON K1V 0Y3

Phone: 613-736-9733 Fax: 613-736-5660

Website: www.cshp.ca

4. U.S. Pharmacopeia

12601 Twinbrook Parkway

Rockville MD 20852 1790

Phone: 800-277-8772 or 301-881-0666

Website www.usp.org

5. Login Brothers

300 Salteaux Crescent

Winnipeg, Manitoba R3J 3T2

Phone: 800-665-1148 Fax: 800-665-0103

Website: www.lb.ca

6. King Guide Publications

King Guide Publications, Inc.

PO Box 10317 Napa, CA 94581

Phone: (707) 257-7573 Fax: (707) 257-7566

Website: www.kingguide.com

Appendix 2.2 References:

1. Ontario College of Pharmacists - Sterile Compounding: A guide for Community Pharmacists, 2003;
2. The Nova Scotia College of Pharmacists - Council Policy: Sterile Compounding, 1999;
3. Prince Edward Island Pharmacy Board Policy Statement - Sterile Compounding, 2001;
4. Wyoming Board of Pharmacy regulations Chapter 13, 2003;
5. Canadian Society of Hospital Pharmacists Guidelines for Preparation of Sterile Products in Pharmacies@ 1996;
6. American Society of Health-System Pharmacists Guideline on Quality Assurance for Pharmacy-Prepared Sterile Products@, 2000;
7. California Society of Health-system Pharmacists Guidelines for Sterile Compounding, 2003;
8. Colorado State Board of Pharmacy guidelines 2003;
9. School of Pharmacy, University of North Carolina "Sterile Compounding Techniques", 2003

Appendix 3:

Refer to CSHP "Guidelines for Preparation of Sterile Products in Pharmacies;"

Appendix 4:

Refer to CSHP "Guidelines for the Handling and Disposal of Hazardous Pharmaceuticals (Including Cytotoxic Drugs)"

A copy of the most recent Canadian Society of Hospital Pharmacists Guidelines for sterile product preparation and handling of disposal of hazardous pharmaceuticals the Society's publication can be ordered from:

Canadian Society of Hospital Pharmacists
1145 Hunt Club Road, Suite 350
Ottawa, Ontario K1V 0Y3
Phone: (613) 736-9733
Fax: (613) 736-5660