The College of Naturopaths of Ontario

Guidelines

Sterile Compounding of Injectables

Adapted from the Ontario College of Pharmacists' Sterile Compounding: A Guide for Community Pharmacists

Introduction

Under the Regulated Health Professions Act, 1991, Naturopathic Doctors are authorized to prescribe, dispense, compound and sell a drug listed in regulation, as well as administer a substance by injection or inhalation. As such Naturopathic Doctors who perform these authorized acts may be required to create unique solutions for injection by any route of administration, and prepare such products which require sterile compounding. Naturopathic Doctors can compound sterile drugs listed on Tables 1, 2 & 5 of the Controlled Acts Regulation if they have the knowledge, skill and judgment and facilities necessary to ensure that the products are prepared in a non-contaminated environment, free of particulate matter. The improper compounding of sterile products can lead to serious consequences for patients in clinical and hospital settings. Naturopathic Doctors should be aware of the importance of technique, staff education, appropriate facilities, and proper monitoring to maintain the safety of products for patient care.

Aseptic Preparation Area

A sterile compounding service in a Naturopathic Doctor's practice can be established and operated within a reasonably small area if it is well planned and organized. The aseptic preparation area may be a separate room, or located in a low or controlled traffic area with limited access. Ideally, the area should be adjacent to any dispensary, clean and free from excess clutter and debris. The Canadian Society of Hospital Pharmacist's standards for an aseptic preparation area should be followed. Storage shelves, refrigerators, sinks, etc., should be located in a separate, adjacent area to help reduce possible contamination. Inventory in the aseptic area should be kept at minimal level and no exterior packaging of drugs should be present. Materials such as needles, syringes and alcohol swabs can be kept in the preparation area but only at minimal levels. Activities such as gowning/gloving (if needed), hand washing and disinfecting should be done in a separate area with clear, posted guidelines and procedures.

Laminar Air Flow Hood

All sterile compounding for Intravenous Infusion Therapy (IVIT) should be performed in a laminar air flow hood. When preparing sterile compounds for injection, for routes of administration other than IVIT (i.e. Intramuscular, Subcutaneous etc..), the member should use their knowledge, skill and judgment to determine whether a Laminar air flow hood should be utilized. These hoods are designed to reduce the risk of airborne contamination during the preparation of sterile products. When working under a laminar air flow hood, the following guidelines should be followed to ensure proper use:

- The hood should be turned on at least 30 minutes prior to use;
- The working counter top and sides should be cleaned with a suitable disinfectant prior to and after each use;

- Any bottles, vials or containers should be wiped down with alcohol or disinfectant before being brought into the hood to prevent possible contamination;
- Objects placed in the hood should be suitably placed to provide good air flow with minimal obstruction;
- The High Efficiency Particulate Air filter should be checked, cleaned and re-certified once a year; and
- It is suggested that anyone working under a hood be gowned, gloved and masked. A lab coat should be work to protect the operator from spills and, if hair is long, a suitable cap should be worn.

Aseptic Technique

Aseptic technique is defined as procedures that will minimize the chance of contamination with microorganisms. Contaminants may be brought into the aseptic area by equipment, supplies, or people, so it is important to control these factors during preparation. The following guidelines should be followed:

- Anyone using the laminar air flow hood should wash their hands with a suitable antimicrobial at the beginning of their work and when re-entering the aseptic preparation area;
- Appropriate dress (i.e. gown, gloves or mask if needed) suitable for sterile preparation should be worn;
- Activities unrelated to product preparation should be kept to a minimum;
- Eating or drinking, or the storage of food, drinks or personal items should not be allowed into the aseptic area;
- Only one person should be working in the laminar air flow hood at any given time;
- All items that will be used during preparation should be checked for defects and expiry dates prior to use;
- All non-sterile item surfaces should be disinfected with an appropriate disinfectant prior to being placed into the hood;
- All items necessary for the preparation should be placed into the hood prior to commencing the compounding;
- Direct contact between a sterile product and any non-sterile product should be avoided;
- All non-sterile surface areas should be swabbed with alcohol (70% isopropyl) and left for 30 seconds before puncturing. This includes ampoules, vials and intravenous solution portholes.
- Ampoules and vials should be opened and contents aspirated using appropriate techniques to avoid particulate contamination;
- Needle entry into vials with rubber stoppers should be done at a 45 degree angle to minimize rubber core particulates;
- Filter needles should be considered for use with ampoules;
- All finished products should be carefully inspected for visible precipitation. This should be done outside the laminar air flow hood.
- Each prepared sterile product should be assigned an expiry date based upon available data. If none is available, a short period should be applied (e.g. 24 hours) based upon manufacturer's recommendations, pharmaceutical texts, professional literature, or in-house stability/sterility studies.

Summary

Sterile Compounding should not be attempted if products cannot be compounded properly, and it should only be done using the drugs listed on Schedule 4 of the Controlled Acts Regulation. Naturopathic Doctors should review their resources to determine if sterile compounding is a service they wish to offer.

Resources and References

Controlled Acts Regulation
Food and Drug Regulation
Naturopathy Act, 2007
Ontario College of Pharmacists' Sterile Compounding: A Guide for Community Pharmacists
Professional Misconduct Regulation
Regulated Health Professions Act, 1991
The Canadian Society of Hospital Pharmacists (CSHP) Guidelines for Preparation of Sterile Products in Pharmacies