

Personnel Cleansing and Garbing

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INTRODUCTION

By itself, strict adherence to aseptic technique cannot prevent microbial contamination during the compounding of sterile preparations. Personnel behavior and proper garb are also critical factors that are covered in this chapter. However, this chapter does not cover the use of personal protective equipment (PPE) or garb for handling hazardous drugs (Chapter 12), personnel education about garb (Chapters 23 and 24), or microbiological evaluation of personnel garbing (Chapter 30).

PERSONNEL PREPARATION

Proper preparation for compounding sterile preparations includes personal dress and grooming. The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major steps in preventing microbial contamination in compounded sterile preparations (CSPs).¹ Squamous cells are normally shed from the human body at a rate of a million or more per hour, and those skin particles are laden with microorganisms (**Table 10-1**).

For nearly 200 years, cleansing hands with an antiseptic agent has been recommended to prevent transmitting contagious diseases to patients. See **Table 10-2** for a summary of garbing and cleansing standards in USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations.

HEALTH STATUS

When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or wear cosmetics, they shed skin particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial

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Table 10-1.
Human Particle Generation Rate (>0.3 µm/min)

Motionless/sitting/standing	100,000
Head, arm, neck, leg motion	500,000
All of above with foot motion	1,000,000
Standing to sitting position and vice-versa	2,500,000
Walking at 2 miles/hr	5,000,000
Walking at 3.5 miles/hr	7,500,000
Walking at 5 miles/hr	10,000,000

Source: Adapted from Eudy J. Human contamination. *Am Assoc Contain Control*. 2003; 6:7-11.

Table 10-2.
Summary of USP Chapter <797> Garbing Standards

Garbing Standard Risk Exemption	Low, Low with 12-hr BUD, Medium, and High Risk	Immediate-Use	Allergen Extracts
No skin or respiratory conditions	Yes	No	No
No outdoor garments	Yes	No	No
No makeup or artificial nails	Yes	No	No
No head, neck, or hand jewelry	Yes	No	No
Shoe covers or dedicated shoes head and facial hair covers, mask/eye shield	Yes	No	Head and facial hair covers, mask/eye shield
Hand cleansing	Yes	No	Yes
Low-shed gown	Yes	No	No
Alcohol hand rub	Yes	No	Yes
Sterile, powder-free gloves	Yes	No	Yes
Routine application of sterile 70% IPA during compounding	Yes	No	No

BUD = beyond-use date; IPA = isopropyl alcohol.