Usp 797 guidelines 2020 pdf

This chapter describes the minimum standards to be followed for the preparation of compounded sterile preparations (CSPs) for human and animal drugs. Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see Sterile compounding differs from nonsterile compounding (see Pharmaceutical Compounding—Sterile PreparationsINTRODUCTION AND SCOPE. This chapter describes the minimum standards to be followed for the INTRODUCTION. The requirements in this chapter must be followed to minimize harm, including death, to human and animal patients that INTRODUCTION AND SCOPE. The following represents key changes from the currently enforceable version of USP Chapter > (last major revision in) to the revised USP Chapter INTRODUCTION. The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial Pharmaceutical Compounding — Sterile Preparations Revision Bulletin level for air, surface, and personnel gear are not exceeded for a specified cleanliness classSterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication. This chapter provides procedures and requirements for compounding sterile preparations. KEY CHANGES.

Difficulté **Très facile** | Durée **211 jour(s)** | Catégories **Électronique, Musique & Sons, Robotique** | Coût **20 USD ($)**

Sommaire

Matériaux

Outils

Étape 1 -