Verifications, not validation, is what is required. Verifications involve checking to ensure that all the processes were appropriate and accurately performed. Validation is much more involved and time-consuming.

**Patient Counseling**

As with any prescription, patient counseling is important. It is especially important with compounded preparations where the beyond-use date may be shorter. Patients should be counseled about use, storage and evidence of instability (visu-
al changes, odor, etc.).

**SUMMARY**

There is no question that the standards of the USP serve to enhance patient safety and also protect the pharmacy. There are many general principles in the USP that either directly or indirectly affect phar-

maceutical compounding. The primary chapters are <795> Pharmaceutical Compounding—Nonsterile Prepara-

tions, <796> Pharmaceutical Compounding—Sterile Prepara-

tions, <1007> Good Compounding Practices, and <1057> Pharmacol-

OGIC Calculations in Prescription Compounding. In the next issue, we will discuss the rationale behind and the practical application of USP <796>.

**REFERENCES**

2. U.S. Pharmacopoeial Convention, Inc. USP-Phar-


**GOALS AND OBJECTIVES**

1. The first US Pharmacopeia was established in 1820 by a group of: A. owner B. pharmacist C. government agent D. technician E. all the above

2. Approximately how long did it take you to read the Secundum Artem? a. 6 months b. 3 months c. 2 months d. 1 week e. 1 day

3. The ultimate responsibility for compliance with all the USP/NF standards is: A. I only B. II and III only C. I and II only D. II and III only E. none of the above

4. What is USP Chapter <795>? Why should compounding pharmacies be familiar with it? Where did it come from? From whom did it derive its authority? Do I have to follow it? What happens if I don't? Is it really important? What if I have never had a problem before...do I still need to comply with its standards? Who evaluates these standards? Are they "set in stone" or do they change? What is the relationship between the USP and the Food and Drug Administration? Do the USP standards really contribute to patient safety?

5. If no valid data is available for an active, compounded record can be used to ensure the data when it is to be applied to: A. I only B. II and III only C. I and II only D. II and III only E. none of the above

6. If valid data is available for an active, compounded record can be used to ensure the data when it is to be applied to: A. I only B. II and III only C. I and II only D. II and III only E. none of the above

7. Which of the following is NOT on the checklist for acceptable strength, quality, and potency? A. I only B. II and III only C. I and II only D. II and III only E. none of the above

8. The purposes of the thirteen steps in the Compounding Process are to: I. ensure third party reimbursement II. maximize the prescribers' intent for the patient III. health food/nutrition stores IV. the relationship between the USP and the FDA V. patient harm and/or litigation results

9. Please print address clearly below OR email address:__________________________________________

10. The purpose of the compounding standards of the USP is to: A. I only B. II and III only C. I and II only D. II and III only E. none of the above

**INTRODUCTION**

What is USP Chapter <795>? Why should compounding pharmacies be familiar with it? Where did it come from? From whom did it derive its authority? Do I have to follow it? What happens if I don't? Is it really important? What if I have never had a problem before...do I still need to comply with its standards? Who evaluates these standards? Are they "set in stone" or do they change? What is the relationship between the USP and the Food and Drug Administration? Do the USP standards really contribute to patient safety?

All these are valid questions that deserve an answer. As we travel from looking at where the pharmacopeias came from and from where they derive their authority, we will look at how the USP-NF shapes pharmacy compounding and the pharmaceutical industry today.

**BACKGROUND**

Pharmaceutical compounding is the history of pharmacy, spanning the past 5,000 years, until the early to mid-1900s when the pharmaceutical industry became institutionalized. There are many records written of ancient and modern pharmacy compounding started back in 1590 in Bologna, Italy, when a group of pharmacists gathered in connection with a local book of drug standards. Many pharmacopoeias were developed on local, city, and national levels, with the USP and NF being the only one truly national in scope.
The U.S. Pharmacopeia (USP) was established in January 1820 by a group of pharmacists from the United States led by John Barron. The original purpose of the USP was to establish uniform standards for the medications they prescribed. In 1820, it became official when the U.S. Congress passed a law that required the USP to be used in the United States. The USP convention met every 10 years and produced a compendium of pharmacopeial articles. The first USP convention was held in 1850. There was a change in the USP during the early-mid 1900s as the pharmaceutical industry began to grow. In 1936, the USP created its first standardized formulas including the ingredients and equipment needed to prepare the formulas. Today the USP-NF is published biennially. It is unique because other pharmacopeias throughout the world are prepared by the national levels in Europe. Some of the best known were the British Pharmacopoeia, the United States Pharmacopoeia, and the Japanese Pharmacopoeia.

The USP is an independent organization where decision-making committees are made up of volunteers serving on various expert committees. There are two committees that address compounding; one for nonsterile and one for sterile activities. Each committee consists of 10 to 12 volunteers from pharmacy practice, academia, and the pharmaceutical industry. The committees meet with sufficient frequency to accomplish their goals (usually one to three times per year). Each committee has a staff liaison at USP that is responsible for working with the committees.

The USP was mentioned as a “standard” in the Drug Import Act of 1848 and the USP and NF were both established as official compendia for the United States in the Pure Food and Drug Act of 1906. It's status continues today. In 1906, the Food and Drug Administration (FDA) was born, having originally been the Food and Drug Bureau of Agriculture and then the Food, Drug and Insecticide Administration and finally the FDA. The FDA is the federal regulatory body established by the USP for the pharmaceutical industry or the standards it develops. The USP is independent and is not subject to any federal regulation or oversight by the FDA. It is unique because other organizations throughout the world are controlled by the government of the country, but not the USP.

The National Formulary (NF) was first published in 1856 by the American Pharmaceutical Association. It consists of standardized formulas including the ingredients and their quantities required for compounding purposes. In 1946, the USP changed from a 10-year to a 5-year meeting cycle to adapt more rapidly to change. In 1975 the USP purchased the NF and in 1980 the first combined USP-NF was published and continues to be published biennially. The standardized formulas were implemented in 1980. Today the USP-NF is published biennially. There was a change in the USP during the early-mid 1900s as the pharmaceutical industry began to grow. In 1936, the USP created its first standardized formulas including the ingredients and equipment needed to prepare the formulas. Today the USP-NF is published biennially.

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The National Formulary (NF) was first published in 1888 by the American Pharmaceutical Association, listing the USP was mentioned as a “standard” in the Drug Importation Act of 1848 and the USP and NF were both published the book every 5 years. In 2002, annual revision to the book; pharmacists were invited to join in the USP convention met every 10 years and produced a book, the committees were invited to join the USP.

The USP is an independent organization where decisions about standards are made by volunteers, who are experts in their field, and conduct much of their business via telephone, e-mails, etc. Each committee has a staff liaison at USP that is responsible for working with the committees. The USP was mentioned as a “standard” in the Drug Importation Act of 1848 and the USP and NF were both published the book every 5 years. In 2002, annual revision to the book; pharmacists were invited to join in the USP convention met every 10 years and produced a book, the committees were invited to join the USP.

In 1993, there was the formation of the Expert Adviso Panel and the Review Panel on Pharmacy Compounding from an Informational Committee to aid in implementing the USP. The Expert Adviso Panel is divided into two groups, one to work on general chapters and the other to work on compounding procedures. In 1996, the USP published the 27th edition. In 1995, the Food and Drug and Insecticide Administration and finally, the FDA. The U.S. Pharmacopeia (USP) was established in January 2000 and remains so today. The purpose of this section is merely to provide a definition for some terms used in the chapter. The beyond-use date is the responsibility of the compounder for some terms used in the chapter. The beyond-use date is the responsibility of the compounder.
In 1940, the USP changed from the 10-year to a 5-year revision to the book; pharmacists were invited to join in revising the contents. In December 1820, they were asked to provide feedback on the draft of the book, which was then published. The book was revised and updated regularly, and its name was changed to Pharmaceutical Compounders Guide to aid in implementing the Pharmaceutical Compounding Practices from an informational, not a regulatory standpoint

In 1993, there was the formation of the Expert Advisory Panel and the Review Panel on Pharmacy Compounding by the USP. The Expert Advisory Panel is divided into two groups: one to work on general chapters and the other to work on compounding procedures. In 1998, the USP published the first edition of the USP <795>, which serves as the official compendium for compounding pharmaceuticals. The chapter provides guidance to pharmacists and other compounding professionals on proper compounding practices and techniques. When Congress enacted the FDA Modernization Act of 1997 (FDAMA97) that refer to pharmacy compounding, not the time of dispensing. Compounders are responsible for the compounded medicine if a dosage form is used, not the time of dispensing. Compounders are required to have a written policy and procedure to determine an appropriate beyond-use date. In the event there is no data available, the chapter provides guidelines that can be used, as follows:

1. Have the physical and chemical properties, and medicinal, dietary, and pharmaceutical uses of the active drug been reviewed and documented? Are the quantity and quality of each active ingredient identifiable?

2. Will the active ingredients be effectively absorbed, locally or systematically according to the prescribed purpose, from the preparation, and route of administration?

3. Are there added substances, confirmed or potentially confirmed to cause an allergic reaction, which may be expected to cause an allergic reaction, in a way that is not all dosage forms of the same size, shape, and color, and assume a major role in providing pharmaceuticals for their health care as well. These requirements are similar to those for compounding, not the time of dispensing. Compounders are responsible for the compounded medicine if a dosage form is used, not the time of dispensing. Compounders are required to have a written policy and procedure to determine an appropriate beyond-use date. In the event there is no data available, the chapter provides guidelines that can be used, as follows:

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**Introduction**

What is USP Chapter <795>? Why should pharmacists be familiar with it? Where did it come from? From where did it derive its authority? Do I have to follow it? What happens if I don’t? Is it really important? What will I have never had a problem before? Do I still need to comply with its standards? Establishes these standards? Are they “set in stone” or do they change over time? What is the relationship between the USP and the Food and Drug Administration? Do the USP standards really contribute to patient safety?

All these are valid questions that deserve an answer. As we travel from looking at where the pharmacists came from and from where they derive their authority, we will look at how the USP-NF shapes the pharmaceutical compounding industry today. The goal of this article is to provide information on the historical development and practical implementation of USP Chapter <795> Pharmaceutical Compounding-Nonsterile Preparations.

**Background**

Pharmaceutical compounding is the history of pharmacy, spanning the past 5000 years, until the early to mid-1900s when the pharmaceutical industry became formalized. There are many recorded writings of formulas and methods of treating disease in pharmacy history books. The standards for uniformity and quality in pharmacy compounding started back in 1580 in Bergamo, Italy when the first American pharmacists and pharmacists practiced in connection with a local book of drug standards. Many pharmacists were developed on local, city and state levels. This lesson is no longer valid for CE credit after 12/01/08.

**Verification**

Verification, net validation, is what is required. Verification involves checking to ensure that all the processes were appropriate and accurately performed. Validation is much more involved and time-consuming.

**Patient Counseling**

As with any prescription, patient counseling is important. It is especially important with compounded preparations where the beyond-use date may be much shorter. Patients should be counseled about use, storage and evidence of instability (visual changes, odor, etc.).

**Summary**

There is no question that the standards of the USP serve to enhance patient safety and also protect the pharmacist. There are many general chapters in the USP that either directly or indirectly affect pharmacy compounding. The primary chapters are USP Pharmaceutical Compounding-Nonsterile Preparations, <795> Pharmaceutical Compounding-Ready-to-Use Compounds, <787> Good Manufacturing Practices, and <789> Pharmaceutical只 Calculations in Prescription Compounding.

**References**


**GOALS AND OBJECTIVES**

Goal: The reader will be able to: 1. Discuss the various sections of USP Chapter <795> and their application. 2. List the five questions that should be considered concerning each compounded prescription. 3. Describe the relationship between the USP standards and the Food and Drug Administration. 4. Describe the various sections of USP Chapter <795> and their application. 5. List the five basic reasons for developing USP Chapter <795>.

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**USP chapter <795>**

**Current & Practical Compounding Information for the Pharmacist**

**VOLUME 13 NUMBER 4**

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