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The 4th Thailand Hospital Compounding Pharmacy
Annual Meeting 2018
วันที่ 12–13 มีนาคม พ.ศ. 2561
โรงแรม อมารี แอร์พอร์ต ดอนเมือง

Guidelines & Search Tools: Pharmaceutical Compounding

ผศ.ดร.กฤษณ์ สุขนันทร์ธะ
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คณะเภสัชศาสตร์ มหาวิทยาลัยสงขลานครินทร์

Pharmaceutical Compounding

- Pharmaceutical Compounding Guidelines
  - ✓ ASHP
    - Compounding Sterile Preparations
    - Handling Hazardous Drugs
    - Pharmacy-Prepared Ophthalmic Products
  - ✓ USP
    - Nonsterile Compounding <795>
    - Sterile Compounding <797>
    - Hazardous Drugs <800>

Guidelines: Pharmaceutical Compounding

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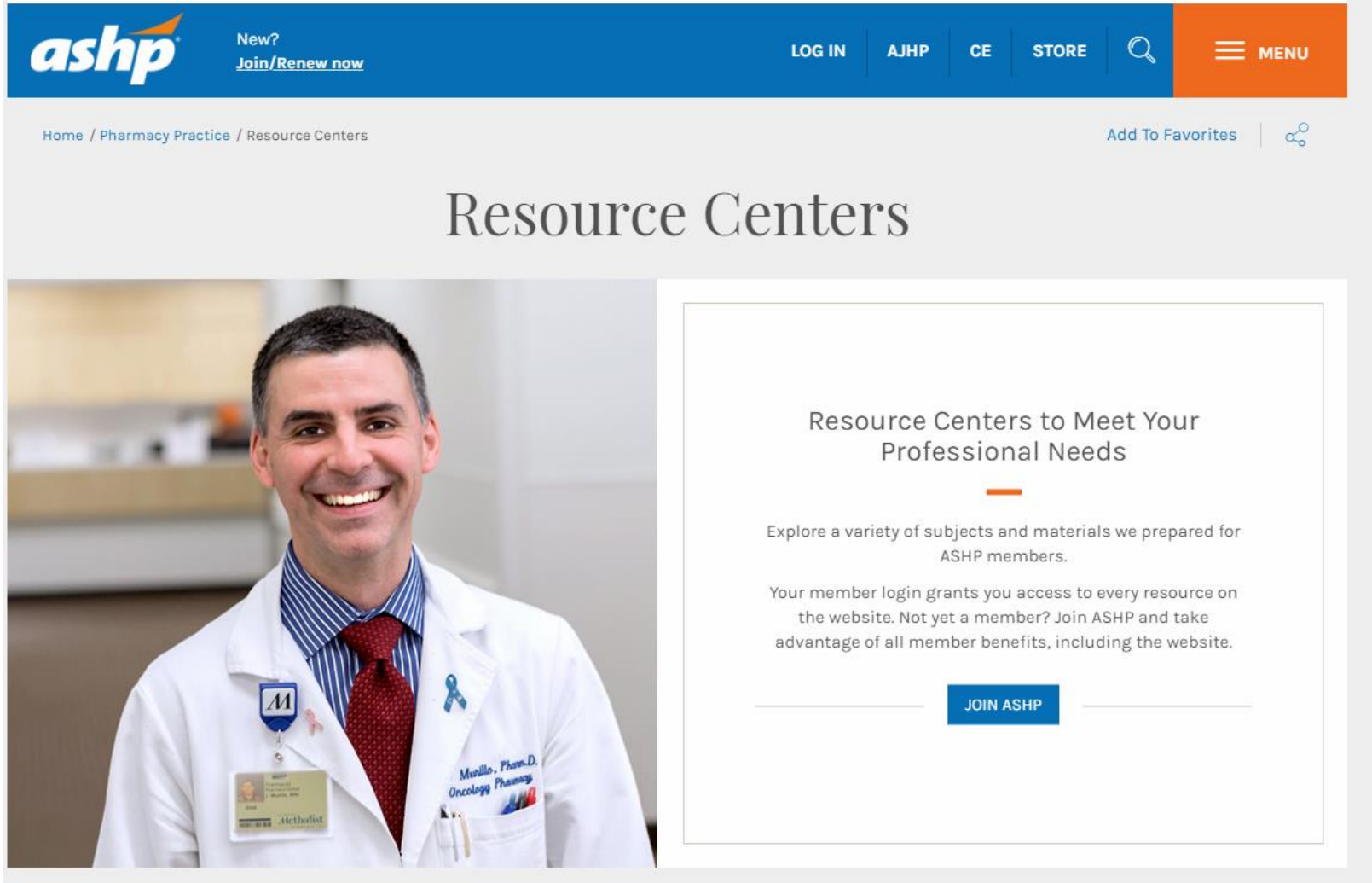

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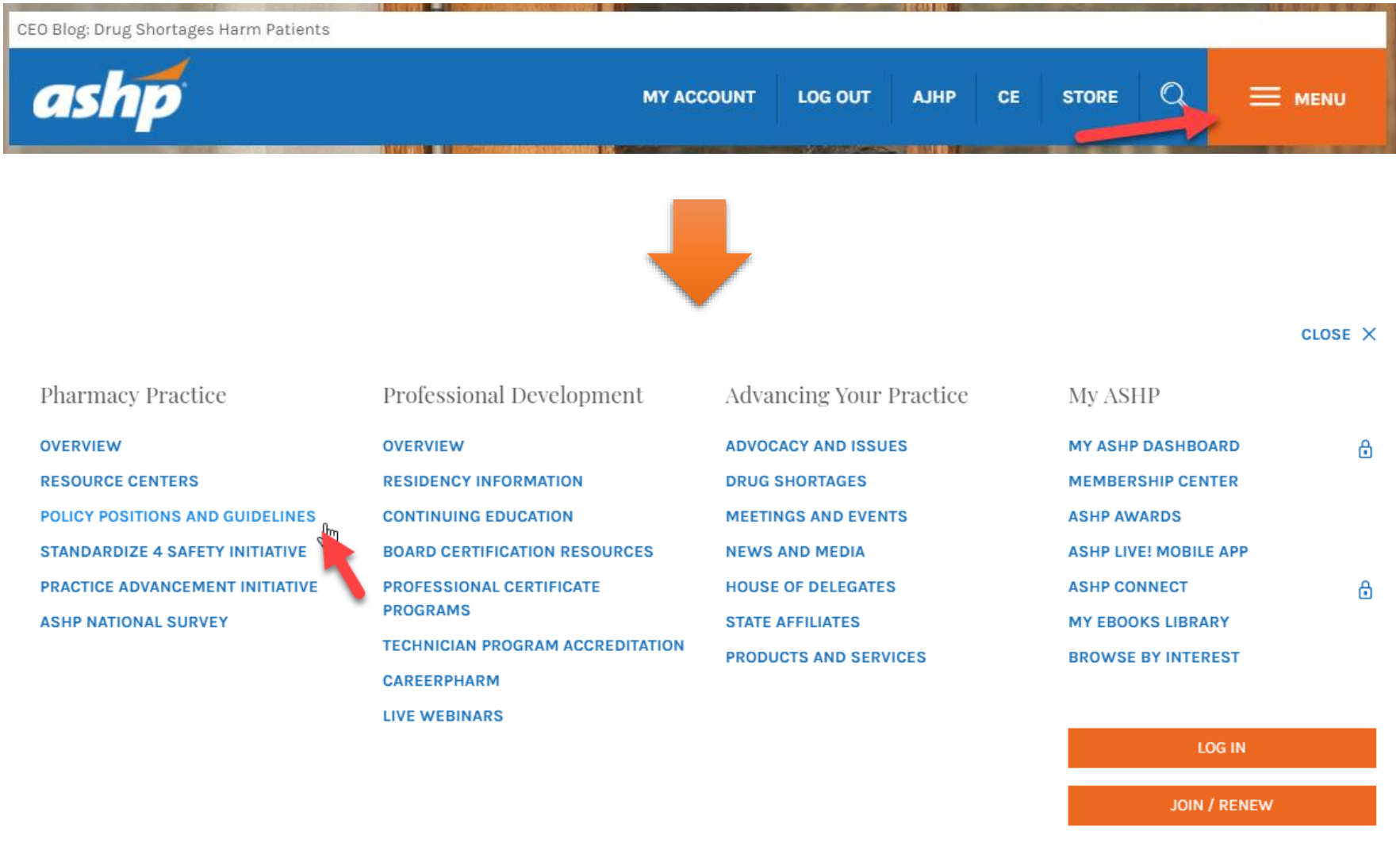

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ASHP Guidelines on Compounding Sterile Preparations

Purpose

The compounding of medications is a fundamental part of pharmacy practice. All compounding personnel, mainly pharmacists and pharmacy technicians, are responsible for compounding and dispensing sterile products and preparations of correct ingredient identity, purity (freedom from physical contaminants, such as precipitates,[1] and chemical contaminants), strength (including stability[2] and compatibility), and sterility and for dispensing them in appropriate containers that are labeled accurately and appropriately for the end user. In contemporary health care organizations, patients receive compounded sterile preparations (CSPs) that are stored for extended periods before use. It has long been recognized that extended storage of CSPs may allow for the growth of a pathological bioburden of microorganisms[3] and

Legal and Regulatory Considerations

Significant legal and regulatory changes have taken place since publication of the previous ASHP guidelines (Figure 1).

At the time of its publication, section 503A of the U.S. Food and Drug Administration Modernization Act (FDAMA) served to define the limits of legitimate compounding.[18] When section 503A of FDAMA was ruled unconstitutional in 2001, the delineation between compounding and manufacturing reverted to earlier regulations based on the Federal Food, Drug, and Cosmetics Act.[19] Under those regulations, compounding is considered part of the practice of pharmacy and in most states, is governed by state law and regulation. Manufacturing is regulated by the federal government through the auspices of the Food and Drug Administration (FDA). In most cases, extemporaneously

Guidelines: Pharmaceutical Compounding

Physical Facilities and Equipment

Design and Functionality Requirements
Facility requirements are intended to establish a safe environment for compounding CSPs. The International Organization for Standardization (ISO) air cleanliness classification of the compounding environment is a critical measure that is affected by facility design.

Expiration and Beyond-Use Dating

A manufacturer's expiration date is the date assigned pursuant to manufacturer testing. The drug product is guaranteed by the manufacturer to be safe and effective up to the listed date when products are stored as described in the product labeling.

Risk Level Classification

In these guidelines, as in previous ASHP guidelines[14] and *USP* chapter 797,[15] CSPs are stratified by potential risk of

Personnel

Personnel Responsibilities
The term *compounding personnel* refers to any individual involved in compounding sterile preparations, regardless of profession. Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, distributed, and disposed of if not used. Emphasis should be on the need to

Packaging and Labeling

Packaging and subsequent labeling are critical to patient safety. Packaging must be appropriate to preserve both sterility and stability until the BUD. Proper labeling requires an understanding of compounding risk levels and how to determine BUDs based on both stability and sterility.

Guidelines: Pharmaceutical Compounding

Home > Store > Product Listing > ASHP Sterile Compounding Competency Library

ASHP Sterile Compounding Competency Library

Currently includes 3 one hour courses for compounding sterile preparations competency assessment.
Bulk discounts apply – see below for price discounts.

More About This Product

- Pre-recorded webinar on the library and admin features
- Preview the course

Home > Store > Product Listing > The Chapter <800> Answer Book

The Chapter <800> Answer Book

This product is available in print or eBook formats. Please choose to the right.

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Compounding Sterile Preparations: ASHP's Guide to Chapter <797> Courses 1, 2, & 3 Package

ACPE Numbers:
0204-9999-12-031-H04-P
0204-9999-12-031-H04-T
0204-9999-12-032-H04-P
0204-9999-12-032-H04-T
0204-9999-12-033-H04-P
0204-9999-12-033-H04-T

Knowledge-based: 3 Credit Hours

Release Date: March 15, 2012

Expiration Date: January 13, 2018

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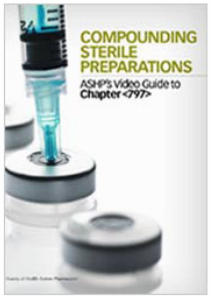

Compounding Sterile Preparations: ASHP's Video Guide to Chapter <797> DVD & Workbook Package

Developed by Patricia C. Kienle, RPh, MPA, FASHP

2009; 106 pages; softbound; 60 minutes DVD
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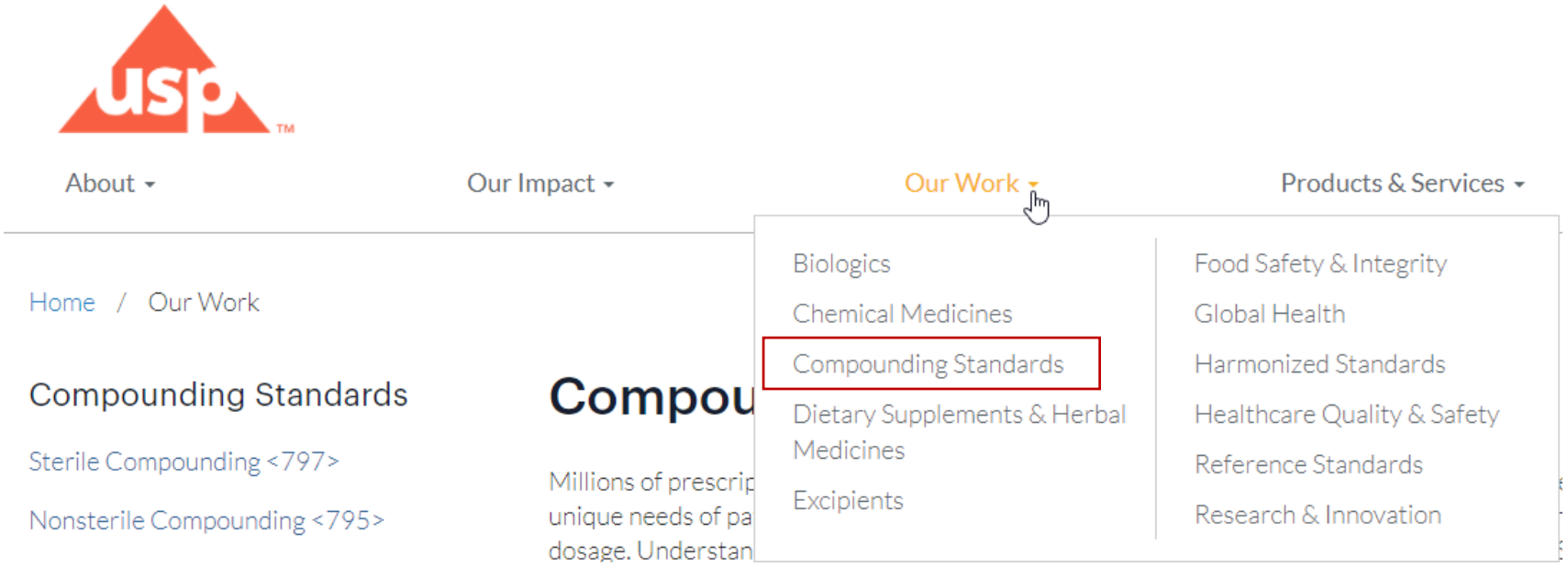

Guidelines: Pharmaceutical Compounding

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USP Compounding Compendium

Compounded Preparations Title Change		
Current Title of Monograph	**Proposed New Title of Monograph**	**PF Proposal**
Acetazolamide Oral Suspension	Acetazolamide Compounded Oral Suspension	40(5)
Allopurinol Oral Suspension	Allopurinol Compounded Oral Suspension	40(5)
Alprazolam Oral Suspension	Alprazolam Compounded Oral Suspension	40(5)
Amiodarone Hydrochloride Oral Suspension	Amiodarone Hydrochloride Compounded Oral Suspension	40(5)
Amlodipine Oral Suspension	Amlodipine Compounded Oral Suspension	40(5)
Atenolol Oral Solution	Atenolol Compounded Oral Solution	40(5)
Azathioprine Oral Suspension	Azathioprine Compounded Oral Suspension	40(5)
Baclofen Oral Suspension	Baclofen Compounded Oral Suspension	40(5)
Bethanechol Chloride Oral Solution	Bethanechol Chloride Compounded Oral Solution	40(5)
Bethanechol Chloride Oral Suspension	Bethanechol Chloride Compounded Oral Suspension	40(5)
Captopril Oral Solution	Captopril Compounded Oral Solution	40(5)
Captopril Oral Suspension	Captopril Compounded Oral Suspension	40(5)
Cefazolin Ophthalmic Solution	Cefazolin Compounded Ophthalmic Solution	40(5)
Chloroquine Phosphate Oral Suspension	Chloroquine Phosphate Compounded Oral Suspension	40(5)
Clonazepam Oral Suspension	Clonazepam Compounded Oral Suspension	40(5)

Example (USP40)

USP40

Contents

Omeprazole Oral Suspension

DEFINITION

Omeprazole Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of omeprazole ($C_{17}H_{19}N_3O_3S$).

Prepare Omeprazole Oral Suspension 2 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Omeprazole and sodium bicarbonate for oral suspension[a] equivalent to	200 mg and 16.8 g
Purified Water, *USP*, a sufficient quantity to make	100 mL

[a] Zegerid 20-mg/1680-mg powder for oral suspension, Santarus, San Diego, CA.

Calculate the required quantity of each ingredient for the total amount to be prepared. Empty the required number of packets in a suitable mortar. Add *Purified Water* in small portions, and triturate to make a smooth paste. Add increasing volumes of *Purified Water* to make an omeprazole liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough *Purified Water* to bring to final volume, and mix well.

ASSAY

• **PROCEDURE**

Solution A: 50 mM monobasic sodium phosphate buffer, adjusted to pH 8.5 with dilute sodium hydroxide

Mobile phase: Acetonitrile and *Solution A* (25:75). Filter and degas.

Standard stock solution: 1.0 mg/mL of USP Omeprazole RS in *Mobile phase*

Standard solution: 50 µg/mL prepared from *Standard stock solution* in *Mobile phase*

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 1.25 mL of Oral Suspen-

USP Monographs

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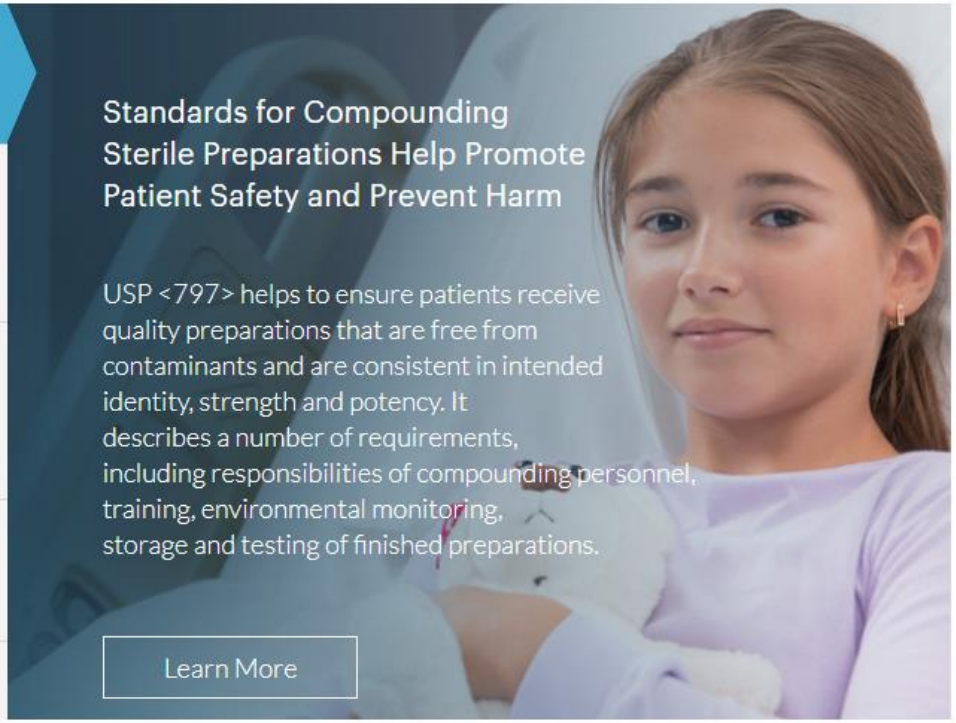
Compounding Standards

Millions of prescriptions are compounded by pharmacists, nurses, and doctors each year in the US to meet the unique needs of patients who otherwise may not have access to the required medicine in the right concentration or dosage. Understanding of the risks inherent in compounding and incorporating established USP standards into everyday practice is essential for patient safety.

Contact Information

compoundingSL@usp.org

- Sterile Compounding <797>
- Non-Sterile Compounding <795>
- Handling of Hazardous Drugs <800>
- Other General Chapters



Guidelines: Pharmaceutical Compounding

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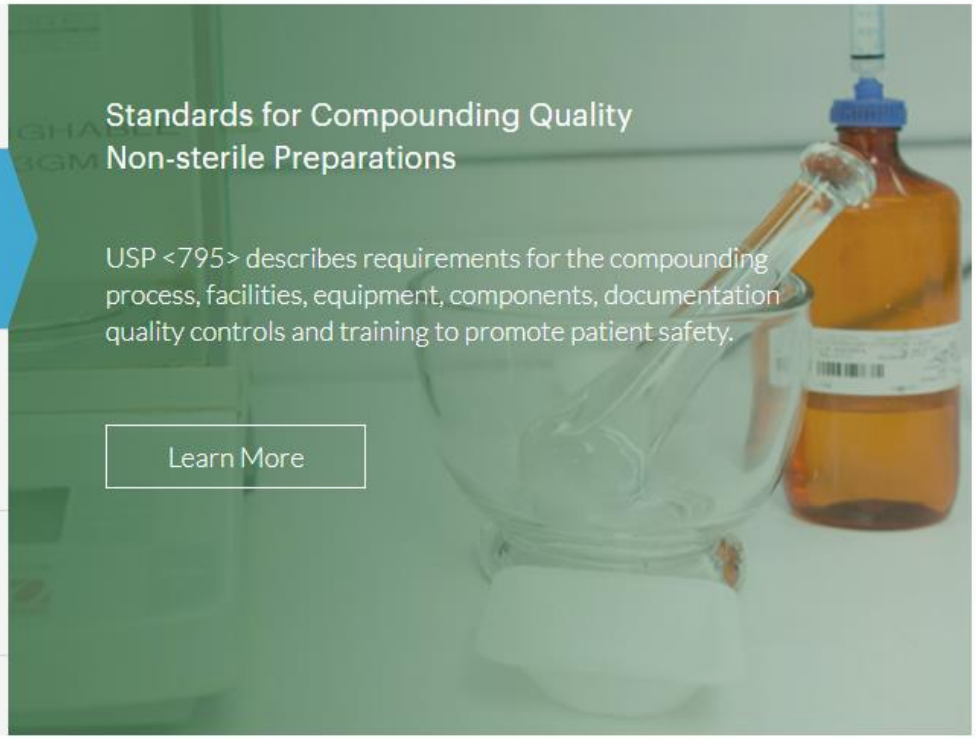

Guidelines: Pharmaceutical Compounding

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Additional USP Standards for Compounding

- <1160> Pharmaceutical Calculations in Prescription Compounding: USP General Chapter
- <1163> Quality Assurance in Pharmaceutical Compounding: USP General Chapter
- <1176> Prescription Balances and Volumetric Apparatus Used in Compounding: USP General Chapter

Learn More

ASHP & USP–NF Guideline

https://goo.gl/ecuiCL

ASHP & USP–NF Guideline

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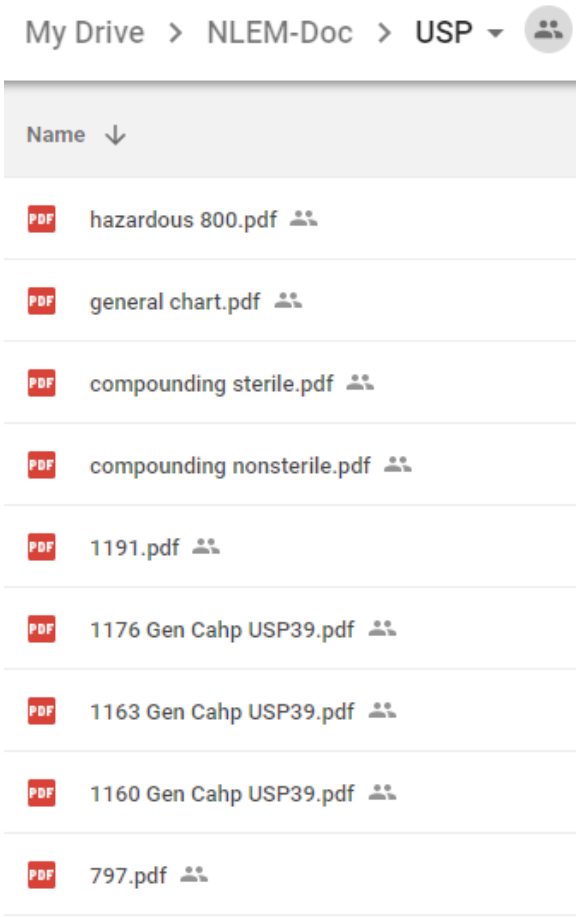

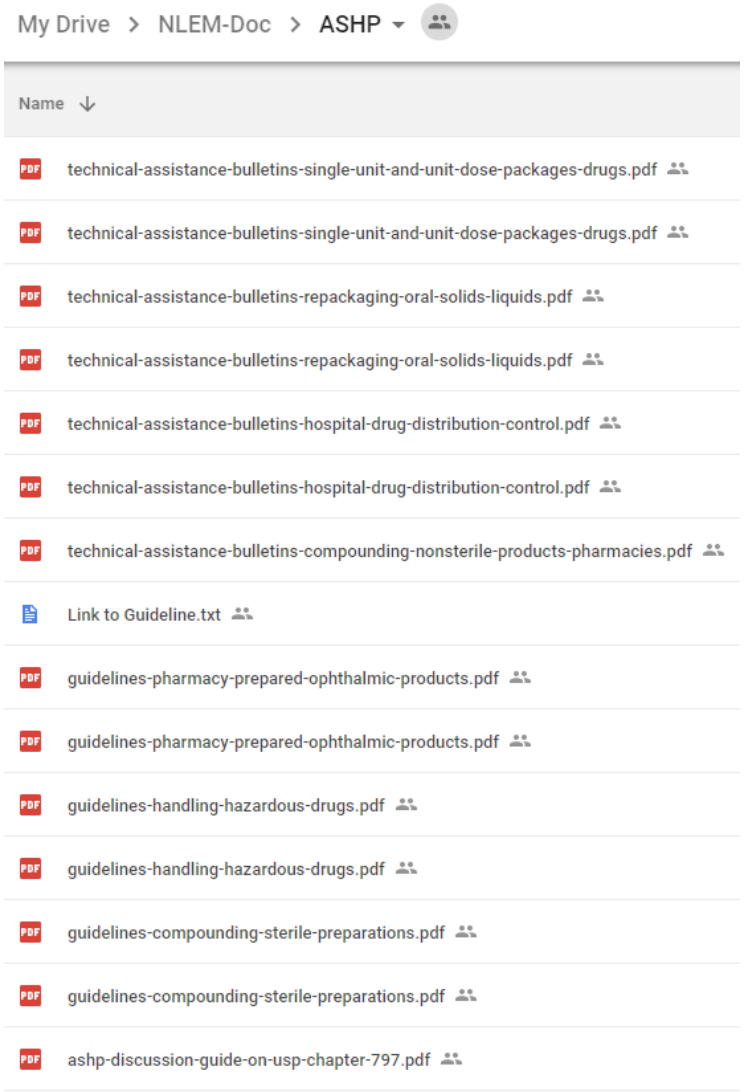

ASHP Guideline (ฉบับภาษาไทย)

http://ccpe.pharmacycouncil.org

บทความวิชาการ

แนวทางการผลิตยาเตรียมปราศจากเชื้อในโรงพยาบาลตาม ASHP Guidelines on Compounding Sterile Preparations

ชื่อบทความ	แนวทางการผลิตยาเตรียมปราศจากเชื้อในโรงพยาบาลตาม ASHP Guidelines on Compounding Sterile Preparations
ผู้เขียนบทความ	ดร.ภก.กฤษณ์ สุขนันทร์ธะ และ ภญ.เปญจมาภรณ์ อภิรมย์รักษ์
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รหัสกิจกรรม	1004-1-000-004-12-2560
ผู้ผลิตบทความ	คณะเภสัชศาสตร์ มหาวิทยาลัยสงขลานครินทร์
การเผยแพร่บทความ	ผู้ประกอบวิชาชีพทุกคน
วันที่ได้รับการรับรอง	27 ธ.ค. 2560
วันที่หมดอายุ	26 ธ.ค. 2561
หน่วยกิตการศึกษาต่อเนื่อง	3.5 หน่วยกิต

การจัดทำหลักเกณฑ์ วิธีการที่ดีในการผลิตยาในโรงพยาบาล

- ASHP + USP–NF Guideline
- Nonsterile Compounding <795> ✓
- Sterile Compounding <797> 

- Hazardous Drugs <800> 

การจัดทำหลักเกณฑ์ วิธีการที่ดีในการผลิตยาในโรงพยาบาล

1. Prepare the test material according to requirements in the monograph or according to specific procedures. If the pH of the test sample is sensitive to ambient carbon dioxide, then use *Purified Water* that has been recently boiled, and subsequently stored in a container designed to minimize ingress of carbon dioxide.
2. Rinse the pH sensor with water, then with a few portions of the test material.
3. Immerse the pH sensor into the test material and record the pH value and temperature.

In all pH measurements, allow sufficient time for stabilization of the temperature and pH measurement.

Diagnostic functions such as glass or reference electrode resistance measurement may be available to determine equipment deficiencies. Refer to the electrode supplier for diagnostic tools to assure proper electrode function.

Where approximate pH values suffice, indicators and test papers (see *Indicators* and *Indicator and Test Papers*) may be suitable.

For a discussion of buffers, and for the composition of standard buffer solutions called for in compendial tests and assays, see *Buffer Solutions* in the section *Solutions*. This referenced section is not intended to replace the use of the pH calibration buffers in *Table 2*.

⟨795⟩ PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS

General Chapters

INTRODUCTION

The purpose of this chapter is to provide compounders with guidance on applying good compounding practices for the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare. This chapter and applicable monographs on formulation help define good compounding practices. Furthermore, this chapter provides general information to enhance the compounder's ability in the compounding facility to extemporaneously compound preparations that are of acceptable strength, quality, and purity. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.

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⟨797⟩ PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS

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 contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see "official" and "article" in the *General Notices and Requirements*) or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* ⟨85⟩), they are potentially most hazardous to patients when administered into the central nervous system.

Despite the extensive attention in this chapter to the provision, maintenance, and evaluation of air quality, the avoidance of direct or physical contact contamination is paramount. It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 (see *Table 1*) areas.

To achieve the above five conditions and practices, this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this chapter do not pertain to the *clinical administration* of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this

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Add the following:

•⟨800⟩ HAZARDOUS DRUGS—HANDLING IN HEALTHCARE SETTINGS

(Chapter to become official July 1, 2018.)

1. INTRODUCTION AND SCOPE

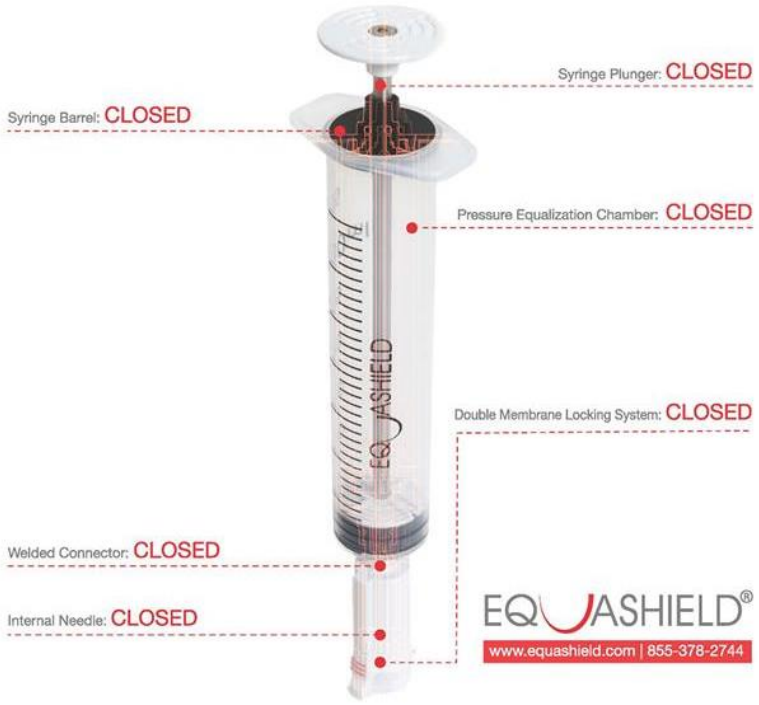
This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.

This chapter applies to all healthcare personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices). Personnel who may potentially be exposed to HDs include, but are not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians.

Entities that handle HDs must incorporate the standards in this chapter into their occupational safety plan. The entity's health and safety management system must, at a minimum, include:

- A list of HDs
- Facility and engineering controls
- Competent personnel
- Safe work practices
- Proper use of appropriate Personal Protective Equipment (PPE)
- Policies for HD waste segregation and disposal

USP 800



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*Equashield does not extend the sterility and use date of the drug beyond manufacturer recommendations. Please refer to individual drug labelling or USP compounding guidelines for beyond use dating of a drug.

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1. CDC Docket number CDC-2015-0075 Proposed Standard for CSTD Testing
2. Clark, Bernadette A. and Sessink, Paul JM. "Use of a closed system drug-transfer device eliminates surface contamination with antineoplastic agents" — Cleveland Clinic Study. Journal of Oncology Pharmacy Practice. 2013 Jun;19(2):99-104.
3. Smith ST and Sdacsky MC. "Syringe plunger contamination by hazardous drugs: A comparative study" – Karmanos Cancer Institute Study. Journal of Oncology Pharmacy Practice. 2014 Oct;20(5):381-5.
4. Fouzia, Berdi, et al. "Assessing the Efficiency of CSTDs for Compounding" — Pharmacy Purchasing & Products. Vol. 12 No. 7. July 2015

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- Compounding Facilities
- Compounding Equipment
- Handling and Storage
- Stability and BUD
- Packaging and Container
- Documentation
- Training and Personnel

การค้นข้อมูลงานวิจัยในโรงพยาบาล

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พระบรมราโชวาทในพระบาทสมเด็จพระเจ้าอยู่หัว รัชกาลที่ ๙

พระราชทานเมื่อปีพุทธศักราช ๒๕๑๘

Search Tools in Pharmaceutical Compounding

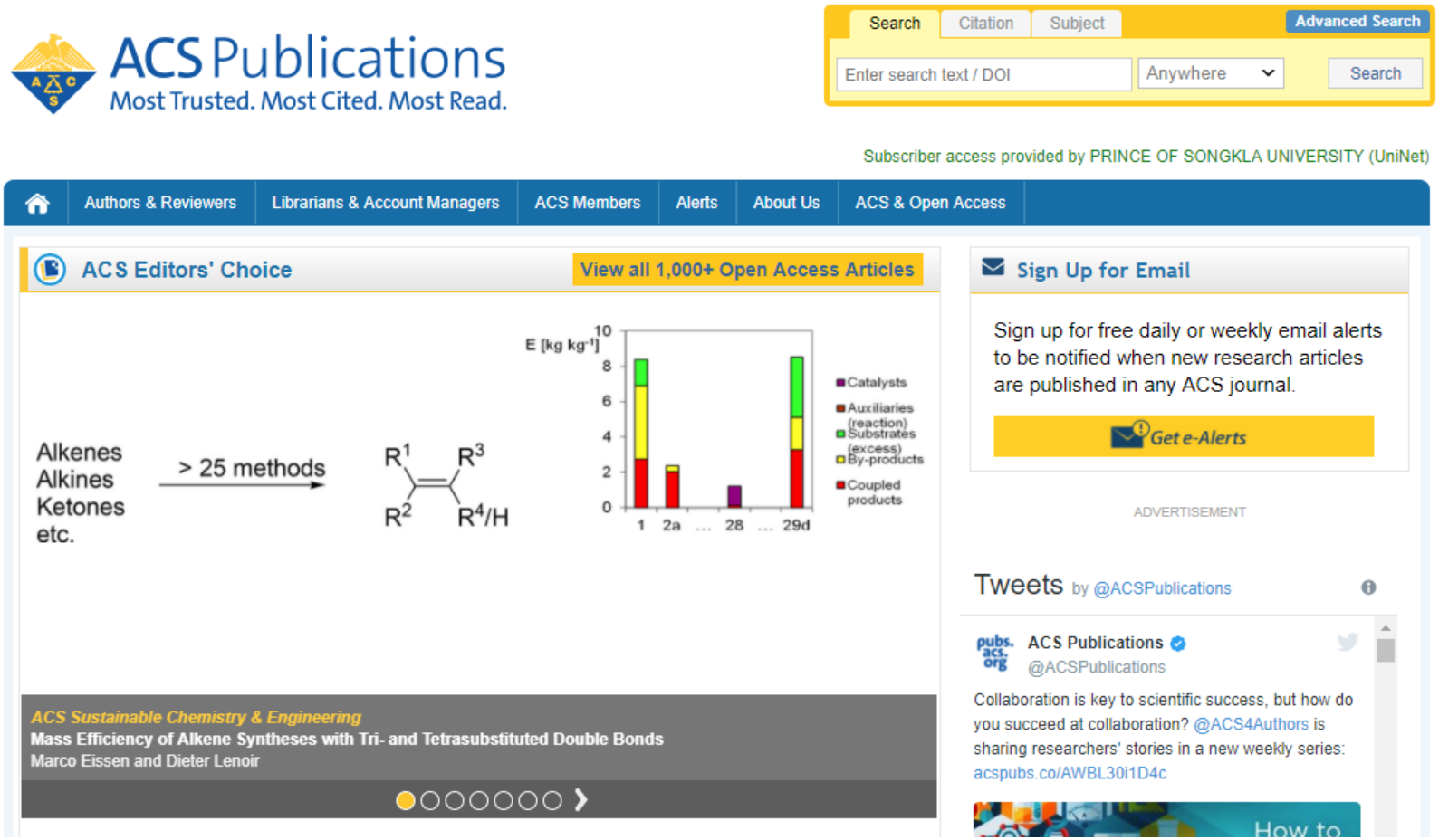
- American Chemical Society (ACS)
- USP–NF (Compounded Monograph & FCC)
- British Pharmacopoeia

} Chemical Purity Grade

- Publisher (Elsevier, Taylor & Francis, Springer, Wiley etc.)
- Standalone journal (IJPC, AJHP etc.)
- MSDS
- Other (stabilis etc.)

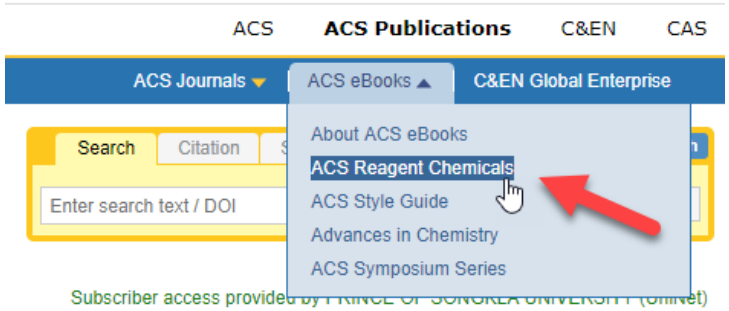
American Chemical Society (ACS)

http://pubs.acs.org



American Chemical Society (ACS)

http://pubs.acs.org



Chemical Purity

1. American Chemical Society (ACS) grade

สารเคมีประเภทนี้เป็นสารเคมีที่มีความบริสุทธิ์สูงที่สุด โดยได้รับมาตรฐานตามเกณฑ์ที่กำหนดโดย American Chemical Society

2. Reagent grade หรือ Analytical Reagent (AR) grade

สารเคมีประเภทนี้เป็นสารเคมีที่มีความบริสุทธิ์สูงซึ่งอาจเทียบเท่า ACS โดยนิยมใช้กันมากในห้องปฏิบัติการและการวิเคราะห์ทางเคมี หากสารเคมีประเภทนี้ผ่านตามเกณฑ์ของ ACS ด้วยก็อาจจะเขียนว่า AR (ACS) reagent

Chemical Purity

3. Pharmacopeia (USP NF BP EP JP) grade

สารเคมีประเภทนี้เป็นสารเคมีที่มีความบริสุทธิ์เป็นไปตามเกณฑ์ที่เภสัชตำรับกำหนด โดยสามารถใช้ในทางอาหาร ทางยา และทางการแพทย์ได้ และมักจะใช้ในปฏิบัติการทั่วไป

4. Food Chemical Codex (FCC) grade

สารเคมีประเภทนี้เป็นสารเคมีที่มีความบริสุทธิ์เป็นไปตามเกณฑ์ที่ FCC กำหนด (ปัจจุบันจะคล้ายกับ USP) โดยกำหนดความบริสุทธิ์ สิ่งเจือปน ซึ่งสารเคมีประเภทนี้จะใช้ในทางอาหาร วัตถุปรุงแต่งอาหาร และสารอาหาร

Chemical Purity

5. Lab grade

สารเคมีประเภทนี้เป็นสารเคมีที่มีคุณภาพสูงและกำหนดปริมาณของสารเจือปนเอาไว้ โดยทั่วไปสารเคมีประเภทนี้จะมีความบริสุทธิ์เพียงพอกับการใช้งานในวัตถุประสงค์ด้านการเรียนการสอน แต่ไม่มีความบริสุทธิ์เพียงพอกับงานทางด้านอาหาร ทางยา และทางการแพทย์

6. Purified grade

โดยมากมักจะเรียกสารเคมีประเภทนี้ว่า practical grade ซึ่งเป็นสารเคมีที่มีคุณภาพดีมีมาตรฐานแต่ทั้งนี้อาจจะไม่ได้อิงตามมาตรฐานสากล สามารถใช้ได้ในวัตถุประสงค์ด้านการเรียนการสอนบางอย่าง แต่ไม่มีความบริสุทธิ์เพียงพอกับงานทางด้านอาหาร ทางยา และทางการแพทย์

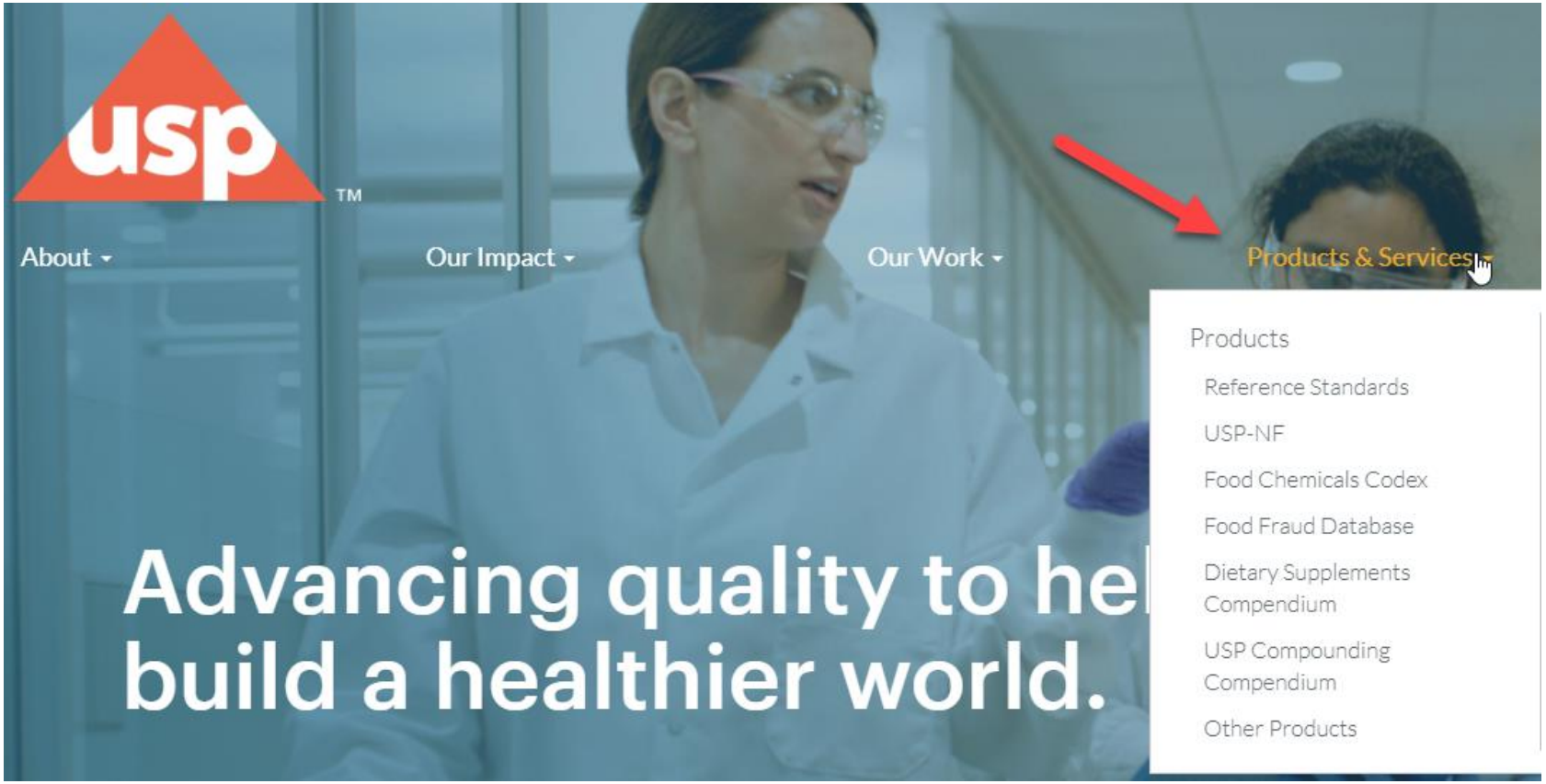
Chemical Purity

7. Technical grade

เป็นสารเคมีที่มีคุณภาพ ใช้ในทางการค้าและอุตสาหกรรม แต่ไม่มีความบริสุทธิ์เพียงพอกับงานทางด้านอาหาร ทางยา และทางการแพทย์

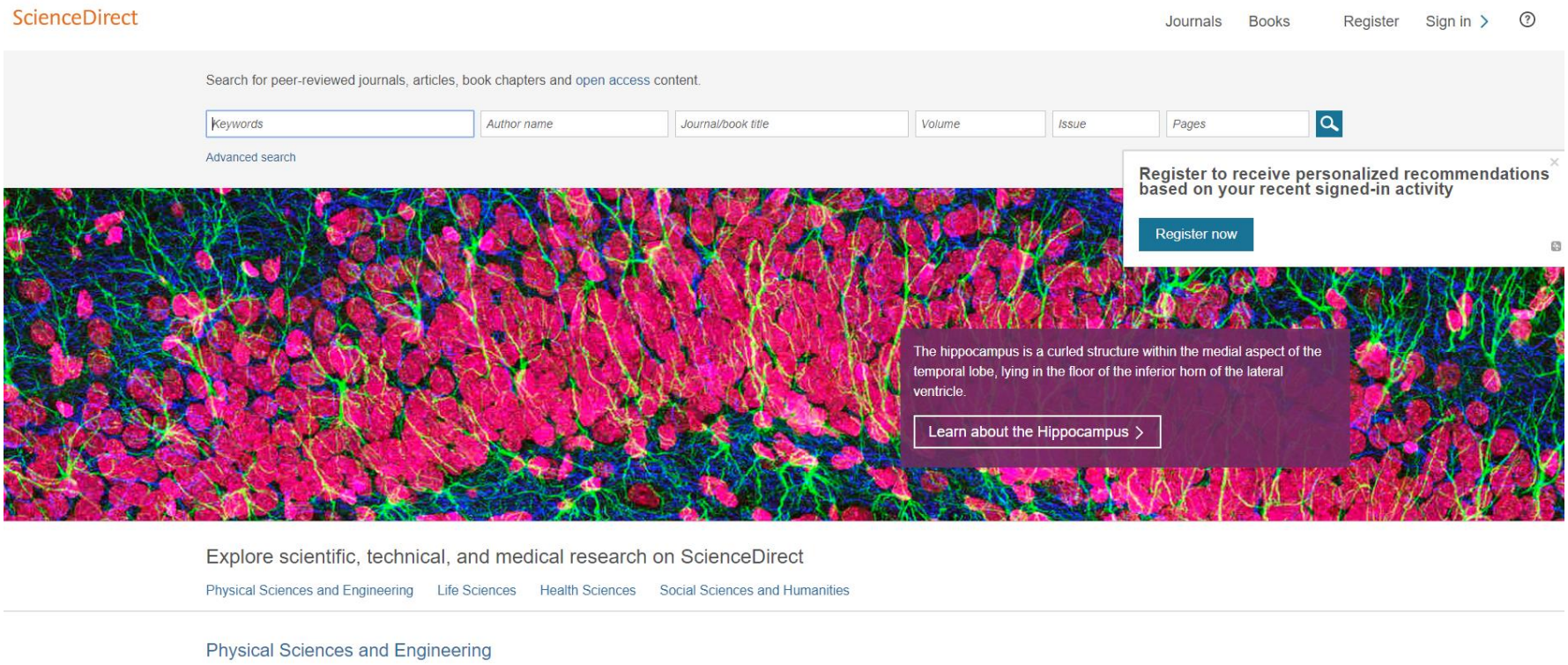
USP–NF & Food Chemical Codex (FCC)

www.usp.org



Elsevier

www.Sciencedirect.com



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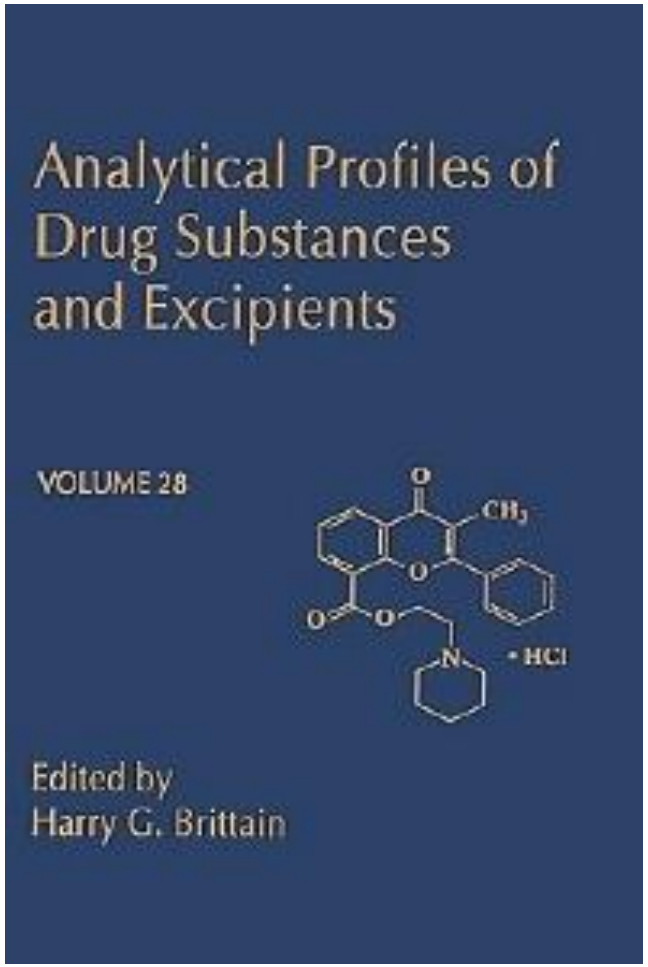
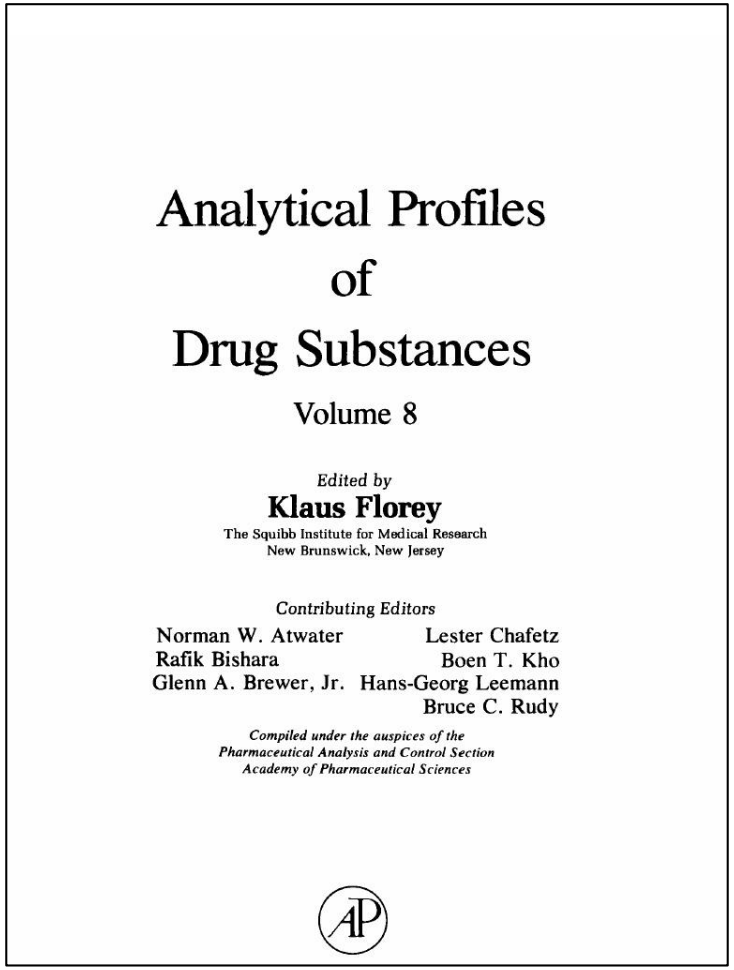
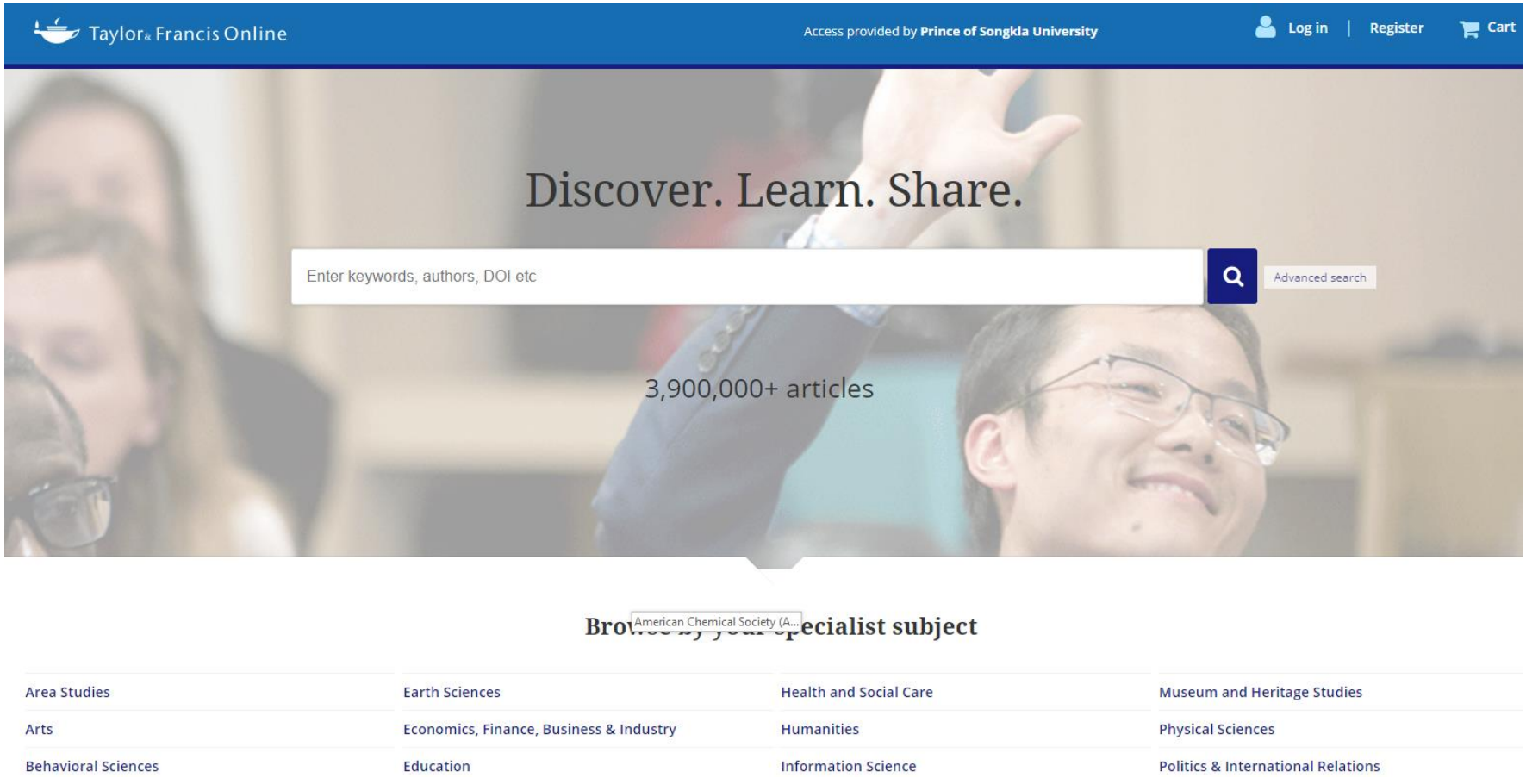




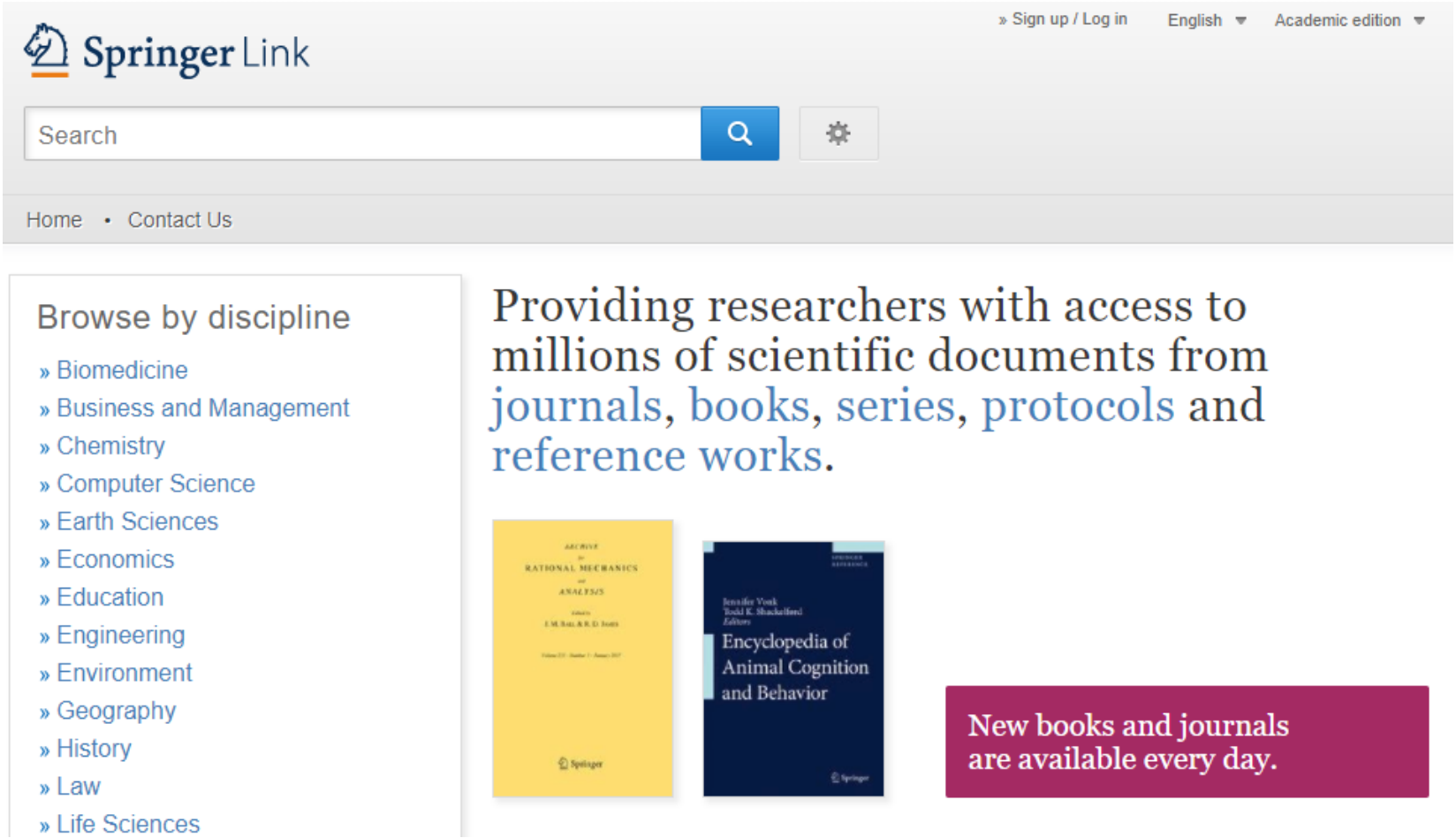
Taylor & Francis

http://www.tandfonline.com



Springer Link

www.springerlink.com



Wiley Interscience

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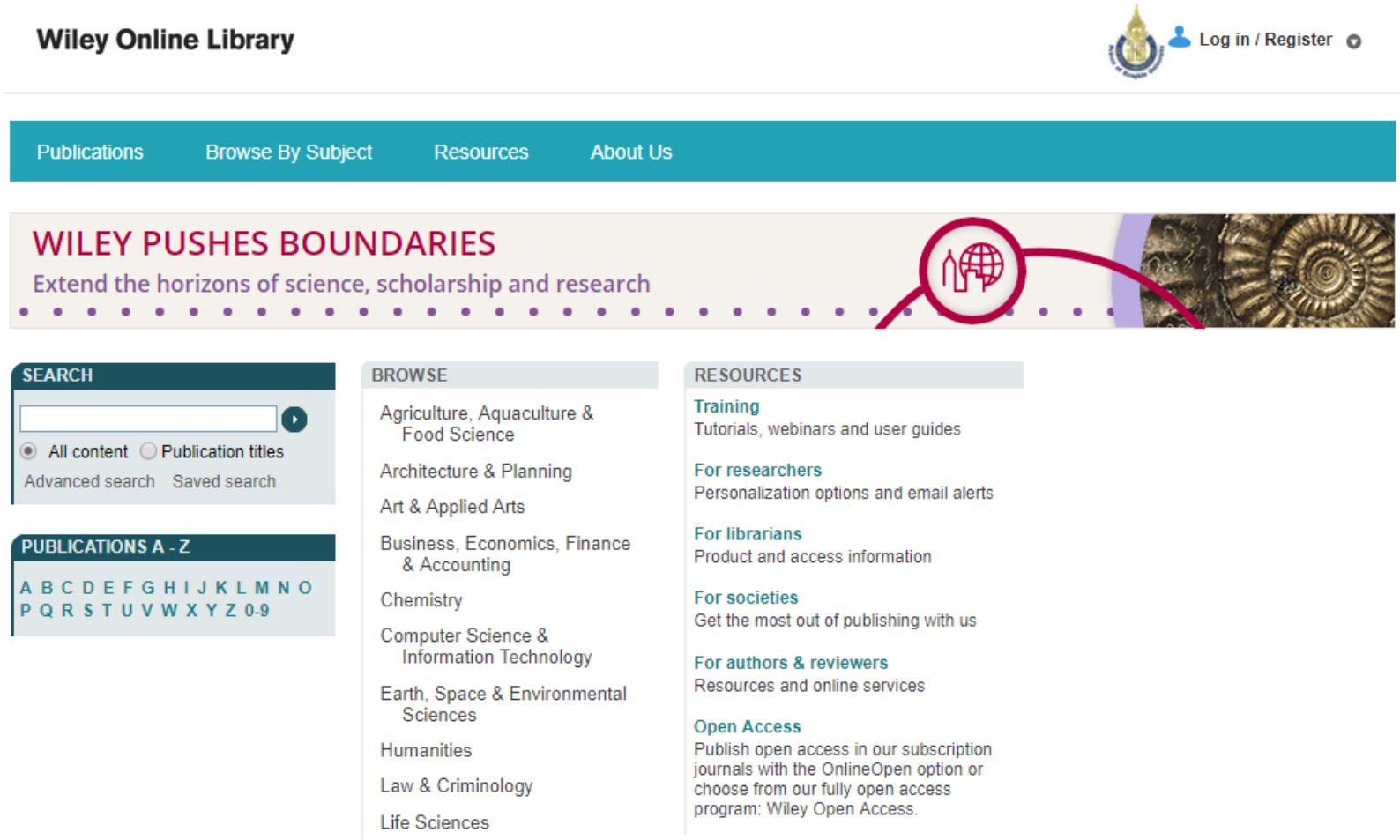

International Journal of Pharmaceutical Compounding (IJPC)

http://www.ijpc.com

International Journal of Pharmaceutical Compounding (IJPC)

http://www.ijpc.com

OFLOXACIN 0.3% OPHTHALMIC SOLUTION

Rx

For 100 mL

Ofloxacin		300 mg
Sodium chloride		850 mg
Benzalkonium chloride		5 mg
Sterile Water for Injection	qs	100 mL

Note: This formulation should be prepared according to strict aseptic compounding technique in a laminar airflow hood in a cleanroom or via isolation barrier technology by a compounding pharmacist who is validated in aseptic compounding. This is a high-risk preparation.

METHOD OF PREPARATION

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Weigh and/or measure each ingredient accurately.
3. Dissolve the ofloxacin and sodium chloride in about 90 mL of Sterile Water For Injection.
4. Add the benzalkonium chloride solution and mix well.
5. Add sufficient Sterile Water For Injection to final volume and mix well.
6. Sterile filter into appropriate sterile containers.
7. Package and label.

PACKAGING

Package in tight, light-resistant containers.[1]

variety of parenteral and nonparenteral pharmaceutical formulations. In parenteral, ophthalmic, and nasal preparations, it is used to prepare isotonic solutions.[4]

Benzalkonium chloride is a bactericidal antimicrobial agent commonly used as a preservative in many ophthalmic, otic, nasal, and parenteral formulations. It occurs as a white or yellowish-white amorphous powder, a thick gel, or gelatinous pieces/flakes with a characteristic mild, aromatic odor, soapy touch, and very bitter taste. It is very soluble in water, alcohol, and acetone. It is hygroscopic, and a 10% w/v aqueous solution has a pH in the range of 5 to 8. Benzalkonium Chloride Solution NF is a clear liquid, colorless, or slightly yellow, unless a color has been added. It has an aromatic odor and a bitter taste. Benzalkonium chloride is composed of a mixture of straight chain homologs that possess different physical, chemical, and microbiological properties. The proportions of these homologs in the mixture determine its effectiveness as a preservative and disinfectant. As a preservative in ophthalmics, it is used in a concentration range of 0.004% to 0.02%, with 0.01% being common.[5]

Sterile Water for Injection is water for injection that has been sterilized and suitably packaged; it contains no added substances. Water for injection is water purified by distillation or by reverse osmosis (RO) and contains no added substances. Note that water for injection is not prepared by an ion-exchange process. Water is a clear, colorless, odorless, and tasteless liquid. Purified water is water that is obtained by distillation, ion exchange, RO, or some other suitable process. Water has a specific gravity of 0.9971 at room temperature, a melting point at 0°C, and a boiling point at 100°C. It is miscible with most polar solvents and is chemically stable in all physical states (ice, liquid, steam).[6]

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http://www.ajhp.org

The Canadian Journal of Hospital Pharmacy

CJHP JCPH

The Canadian Journal of Hospital Pharmacy
Le Journal canadien de la pharmacie hospitalière

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