



U.S. PHARMACOPEIA
*The Standard of Quality*SM



USP: Advancing Public Health through Quality Standards

ANSI World Standards Week
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USP—An Overview

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ **Mission**: To improve the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

- ▶ **What we do**:
 - Develop and provide standards that define the authenticity, identity, purity or impurity of food, drugs and dietary supplements, thus helping to ensure product integrity and the safety of consumers and brands.
 - Since 1820, nonprofit, private, independent, and self-funded
 - Headquartered in Rockville, MD; 600+ employees; facilities in India, China, Switzerland, Brazil
 - Expert volunteers are scientific decision-makers.



USP: A Partner in the Fight Against Counterfeits

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Quality standards defining the authenticity, identity and purity, thus the integrity of

- ▶ Drugs (*United States Pharmacopeia* and the *National Formulary*)
- ▶ Food ingredients (*Food Chemicals Codex*)
- ▶ Dietary supplements (*Dietary Supplement Compendium*)

Promoting the Quality of Medicines (PQM), a dedicated anti-counterfeit program aiding developing countries focusing on

- ▶ Capacity building
- ▶ Education
- ▶ Technical Support and Leadership



Core Compendial Programs

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ The *United States Pharmacopeia* and the *National Formulary* (USP–NF)
- ▶ *Food Chemicals Codex*
- ▶ *USP Dietary Supplements Compendium*
- ▶ Reference Standards
- ▶ Standards for quality criteria (authenticity, identity, purity), test methods for their verification and reference materials from one source.





Contaminated Glycerin



Glycerin and DEG (>800 reported deaths)

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

1937 USA – Sulfanilamide elixir, 107 deaths

Implementation of the FD&C Act in 1938

1969 South Africa – Sedative, 7 deaths

1985 Austria – DEG in wine

1986 India – Medicinal glycerin, 14 deaths

1990 Nigeria – Acetaminophen syrup for children, 40 deaths

1990/92 Bangladesh – Acetaminophen syrup for children, 339 deaths

1995/96 Haiti – Cough medicine, 85 deaths

2006 Panama - Cough and anti-allergy syrup, 116 deaths

2007 Panama –Toothpaste

2008-09 Nigeria –Baby Teething Mixture, 50 deaths
also findings in toothpaste on US market



Excipients, Food: Counterfeit Glycerine

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Occurrence:

Toothpaste and drugs

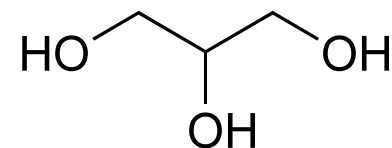
Problem:

Pharma cGMP did not require testing for impurities

Solution:

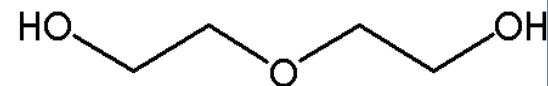
FDA tasked USP to modify standards, DEG testing became mandatory under pharma cGMP

Glycerine (Glycerol)
Edible and GRAS



- Light colored
- Slightly viscous liquid at room temp.
- Sweet taste

Diethylene Glycol
("Antifreeze") POISON!



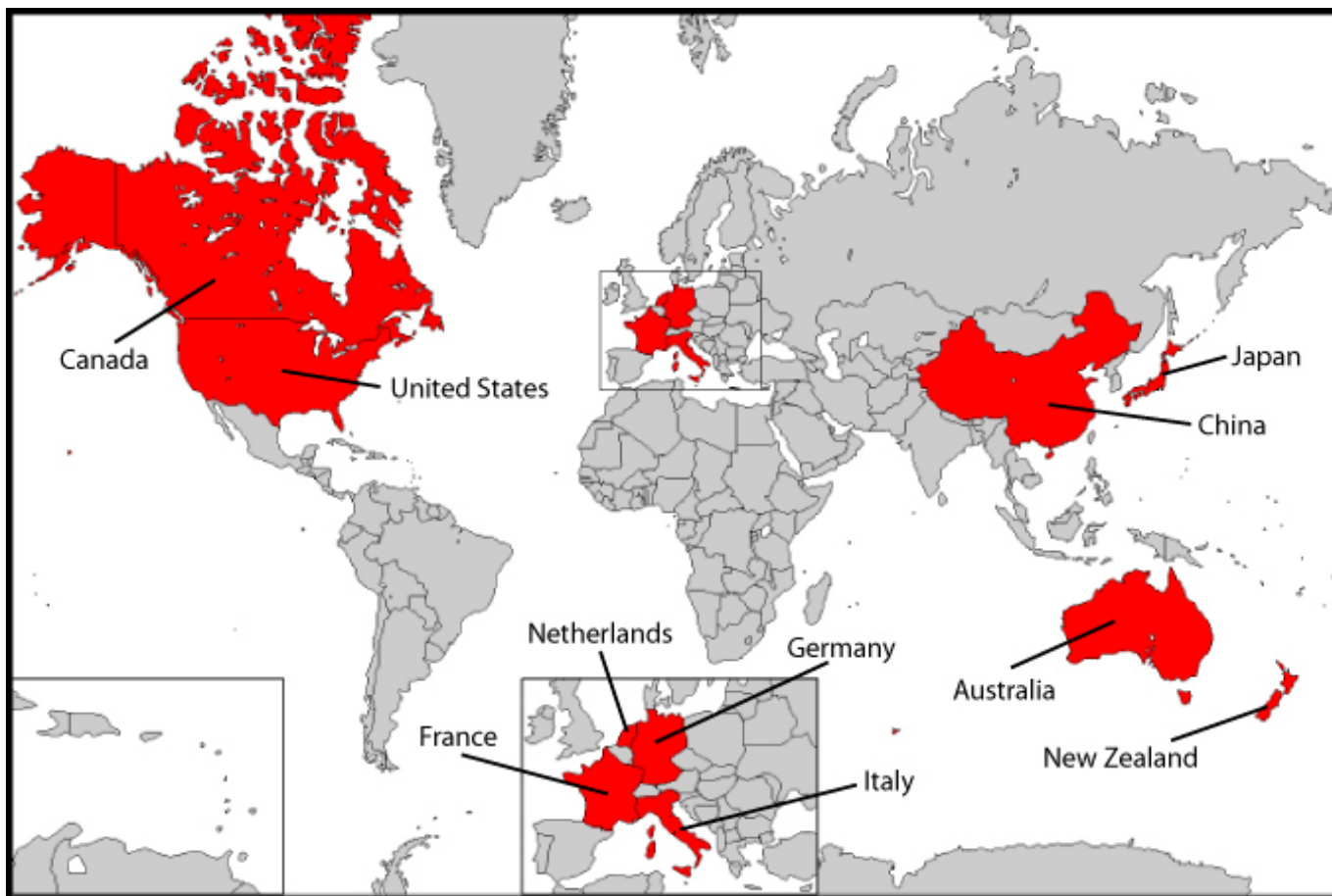


Contaminated Heparin



Drugs: Contaminated Heparin (2008)

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients



Reference: FDA website



Heparin and Oversulfated Chondroitin Sulfate (OSCS)

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Problem: economically motivated adulteration

Heparin: approved drug (blood thinner)

OSCS: adulterant, unknown pharmacological activity, toxic (anaphylactic shock), behaves *in-vitro* like heparin

Solution:

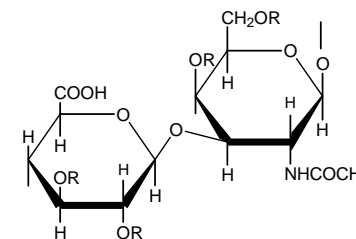
Update of heparin standard ID tests using ^1H NMR, HPLC

Additional Reference Standards:

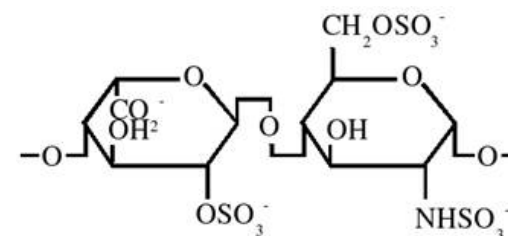
USP Heparin Sodium Identification RS

USP Heparin Sodium System Suitability RS

OSCS



R = SO_3^- or H



Heparin



Combating substandard and counterfeit drugs in developing countries: HIV/AIDS, malaria, tuberculosis



USAID
FROM THE AMERICAN PEOPLE



PROMOTING THE QUALITY OF MEDICINES



PQM Program Objectives

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients



Build capacity & strengthen QA systems

- ▶ Train and educate in quality assurance
- ▶ Establish postmarketing surveillance programs



Help increase supply of QA medicines

- ▶ Improve manufacturers' GMP compliance
- ▶ Test procurement agency samples (UNICEF)



Combat availability of counterfeit meds

- ▶ Provide technical assistance to IMPACT, INTERPOL and other initiatives
- ▶ Raise awareness w/PSAs, campaigns



Provide technical leadership

- ▶ Advocate globally for medicine quality
- ▶ Promote new detection technologies



PQM Countries

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients



Africa

- ▶ Benin, Ethiopia, Ghana, Kenya, Liberia, Mali, Rwanda, Senegal, Tanzania, Uganda



Asia

- ▶ Cambodia, India, Indonesia, Laos, Myanmar/Burma, Nepal, Philippines, Thailand, Vietnam, Yunnan Province of China



Latin America and Caribbean

- ▶ Bolivia, Brazil, Colombia, Ecuador, Guyana, Guatemala, Jamaica, Panama, Paraguay, Peru, Suriname



Europe/Eurasia

- ▶ Russia



PQM Successes in an Ongoing Struggle

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

▶ Sub-Saharan Africa

- One third of antimalarial medicines sampled in three African nations found to be substandard in large-scale USP-WHO study
- Medicine vendors in major Dakar illicit market banished as result of PQM-supported communications campaign in Senegal
- Network of African medicine quality control laboratories (NAMCOL) founded

▶ Southeast Asia

- PSA campaign to raise awareness: www.YouTube.com/uspharmacopeia
- Nearly 65% of illegal pharmacies in Cambodia closed by government in five-month period with assistance from USAID-PQM, WHO
- Philippines national drug quality lab achieved ISO accreditation with PQM support

▶ Latin America and the Caribbean

- Peru national drug quality lab achieved ISO accreditation with PQM support

▶ Europe and Eurasia

- PQM trained 98 Roszdravnadzor analysts in 8 customized lab courses



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Thank You