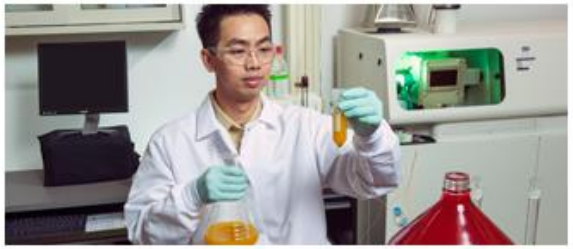
USP Adulterants Database

U.S. Pharmacopeial Convention

USP Adulterants Database



Welcome to the USP Adulterants Database

View | Edit

Dietary supplements, essential to maintaining health and well-being for millions, are being increasingly utilized in fraudulent schemes where rare and expensive ingredients are substituted with substandard and inefficient ones, and synthetic pharmaceutical components are clandestinely added to the formulations without declaration.

USP has assembled reports of dietary supplement adulteration into the USP Adulterants Database, which is intended as a cumulative resource to the laboratory analysts, enforcement agencies and consumers worldwide by raising awareness of ongoing adulteration practices. USP General Chapter <2251>, Screening for Undeclared Drugs and Drug Analogues, is another valuable resource focusing on modern analytical screening methodologies.

Database Predecessors

USP Workshops on DS and Food Adulteration (2011 – 2015)

USP Expert Panel on Adulteration (July 2013 – Present)

USP General Chapter <2251> (Official August 2016)

DS Stakeholder Forums (2011, 2013, 2015)

USP DS Strategic Initiative (2014)

Data Sources

Data from public domain, non-commercial, free access

Primary data streams:

1. Product-focused “Agency reports”:
    a. US FDA
    b. Health Canada
    c. TGA (Australia)
    d. HSA (Singapore)
    e. Others.
2. Ingredient-focused databases: SWGDRUG (DEA), project RESPONSE (Europe), Forendex (Forensic Chemists)
3. Journal Articles – peer-reviewed literature (original and review articles). Typically, target a specific adulterant, or a class of adulterants; may focus on particular analytical methodology.
4. Media reports – industry press, mass media, TV and radio broadcasts. Limited and used to expand context.
5. Specialized literature – court documents, scientific reports, application notes, etc.

Data Related to Adulterants

- Chemical names (including variations, synonyms, and regional spellings). Deduplication!

  Example: sulfosildenafil, thiosildenafil, sildenafil thione, thiodenafil refer to the same single chemical entity

- Identification codes.
  - CAS Number – proprietary, widely recognized, largely uncertain, duplicative
  - UNII Code – Unique Ingredient Identifier; FDA-issued, unique, curated
  - InChI Key – International Chemical Identifier; IUPAC, structure-based

  Correct stereochemistry is crucial.

Other descriptors:

- Adulterant Function
- Chemical Formula
- Molecular Weight

Data Related to Adulterants

References to compendial monographs and external databases:

- USP (and other compendia)
- KEGG Drug – Kyoto Encyclopedia of Genes and Genomes Drug Database
- PubChem ID – popular open chemical database, fair amount of duplication
- ATC Code – Anatomical Therapeutic Chemical Classification (WHO)

Reference Standards: links directly to the USP Store

Figures / structures of relevance

Notes / comments of relevance

Analytical methodologies, links to any additional resources

Data Related to Adulterated Products

1. Intended Uses
2. Declared Ingredients
3. Product Website
4. Companies: manufacturer / distributor / retailer
5. Figures and illustrations
6. Links to the reports in the database

Data Related to Product Recalls

1. Digital Object Identifier (DOI): for print and electronic press
2. Reference Source Type: enforcement report, article, App notes, etc.
3. Reference Source URL: link to the online information
4. Adulterants and Products – all interlinked
5. Recalling Company – as much information about it as reasonably available
6. Additional recall information, attachments – relevant auxiliary data
7. Administrative information – report status

Unique Database Features

1. Strong chemistry and analytics component
2. Curated data
3. Global recall and regulatory action information
4. Additional details:
   - Data related to the manufacturers and retailers
   - Accurate product UPC codes
   - Product trademarks and trademark ownership
   - Information collected from the user forums, Linked-In, social media, blogs, trade press

Benefits to Potential Users

1. Data useful for the activities of regulatory and enforcement agencies, forensic chemists and contract lab personnel.

2. Analytical methodology: hand-picked references to current literature, application notes, compendial monographs.

3. Links to reliable sources of reference materials: USP Store and other suppliers.

4. Accurate chemical information

5. Synergy with similar resources

6. “Submit reports” feature

7. Information is kept current and dynamically updated