



The standard of trust

Welcome



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Digital Documentary Standards

USP's continuing
evolution

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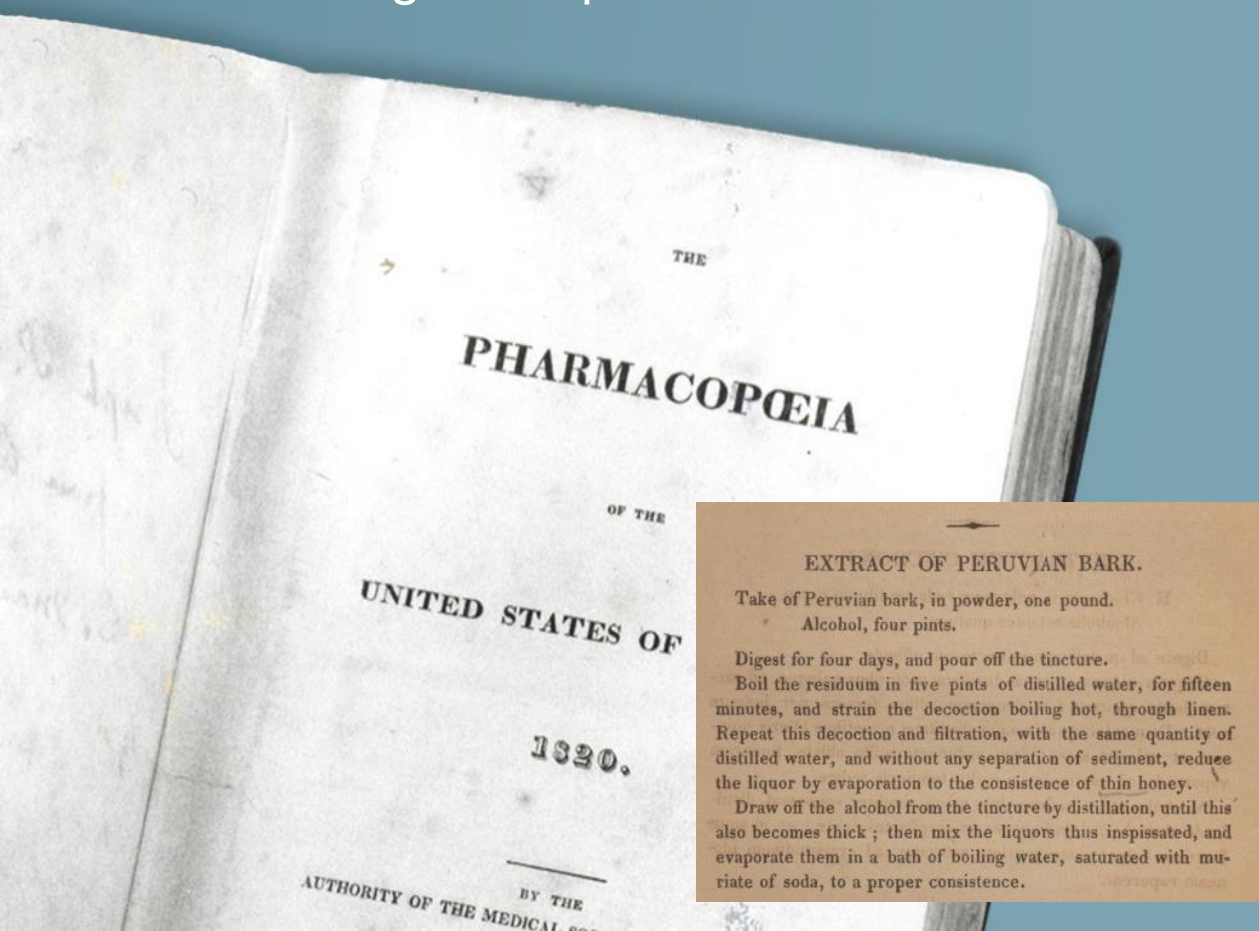


USP: A history of evolution



1820

A single “recipe book”



Today

Sophisticated procedures and acceptance criteria to describe medicinal articles in the marketplace

Heparin Sodium

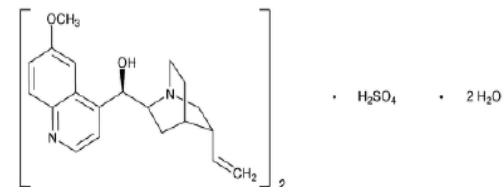
DEFINITION

Heparin Sodium is the sodium salt of sulfated glycosaminoglycans present as a mixture of heterogeneous molecules varying in molecular weights that retains a combination of activities against different factors of the blood clotting cascade.

IDENTIFICATION

- A. 'H N
- B. CHRC
- C. ANTI
- D. MOL
- E. A sc
low co

Quinine Sulfate



$(C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4 \cdot 2H_2O$ 782.94
Cinchonan-9-ol, 6'-methoxy-, (8 α ,9R)-, sulfate (2:1) (salt), dihydrate;
Quinine sulfate (2:1) (salt) dihydrate CAS RN[®]: 207671-44-1.
Anhydrous 746.93 CAS RN[®]: 804-63-7; UNII: M4XCR571WG.

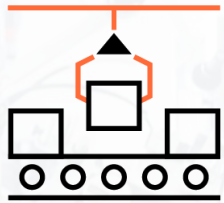
DEFINITION

Quinine Sulfate is the sulfate of an alkaloid obtained from the bark of species of *Cinchona*. It contains NLT 99.0% and NMT 101.0% of total alkaloid salt, calculated as $(C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4$, on the anhydrous basis.

Digitalization is changing the industry



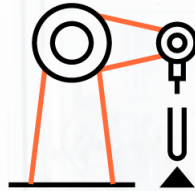
Pharma 4.0



Manufacturing Automation 4.0



Operations Automation 4.0



Laboratory Automation 4.0



Pharma Analytics 4.0



Workforce 4.0



The value of a Pharmacopœia depends upon the fidelity with which it conforms to the best state of medical knowledge of the day. Its usefulness depends upon the sanction it receives from the medical community and the public; and the extent to which it governs the language and practice of those for whose use it is intended.

What we've heard from you



Our analysts are unaware of USP revisions, and keep using old method to test a commodity, until being challenged by client/regulatory agency.

Validation of digital procedures is not a capability we have in house.

An expert user takes hours or days to build a procedure, and we have thousands of procedures.

How can we be sure a chosen system or instrument is suitable for USP testing?

Once we build a procedure, we **MUST** keep it up to date with current USP.

It would be nice to have USP already inside the ELN.



Laboratories experience multiple pain points in translating USP methods into workflows



Key challenges

- ▶ Effort to translate method to workflow/template
- ▶ Calculation errors
- ▶ Missing an update
- ▶ Customized procedures requiring additional validation

Can lead to non-compliance and data integrity concerns/ 483's/Warning Letters...



USP's labs are just like industry labs



- ▶ USP uses
 - USP Monographs and General Chapters to test Reference Standards
 - Written SOP's for how to execute tests from General Chapters
 - Validated spreadsheets to standardize common calculations and documentation
- ▶ Becoming more digital, just like the industry
 - USP uses a commercial Enterprise ELN and CDS today
- ▶ How can USP's lab experience benefit the industry?



Simplify deployment and validation with the USP Monograph Library



What do you need to be able to utilize this future solution?

- ▶ What if there was an industry wide digital library that was
 - Based on the USP standards
 - Vendor Neutral & F.A.I.R. (Findable, Accessible, Interoperable, Reusable)
 - Easily implemented inside of your ELN/LES
 - Kept up to date with latest revisions
- ▶ Staying accurate and current with USP versions potentially reduces compliance deviations.

Browser window: ZONTAL Space, URL: https://sandbox.zontal.cloud/ingest

Page header: Lifecycle Status, Search, Add Filter

1 result

Lifecycle Sta...	Preferred L.a...	Created On	Information ...	Imported fro...	Imported fro...
Transmitted	Devenlafaxi...	2024/Aug/0...	Empower M...		

Create Submission Info...

Information Package Profile: Monograph Archive

Drag and Drop files here, or click to select files

Selected Files - 0 bytes

Provenance

Content identifier: [input field]

Created By (informa... [dropdown menu]

File Explorer window: XML Files

Path: Desktop > XML Files

Name
Amlodipine Besylate Tablets
Amlodipine Besylate
ARGININE HYDROCHLORIDE
ARGININE
Atorvastatin Calcium Tablets
Atorvastatin Calcium API
Azithromycin
Benzalkonium Chloride API
Copovidone
DAPAGLIFLOZIN PROPANEDIOL
Ezetimibe API
Ibuprofen
Lidocaine Hydrochloride
Metformin Hydrochloride
METHIONINE
NIACINAMIDE
Rosuvastatin Tablets
SACCHARIN SODIUM
Sitagliptin Tablets
Trehalose

20 items 1 item selected 143 KB



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Questions



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Stay Connected

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Thank You



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