

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Coimbatore -641035



COURSE NAME: Pharmaceutical Inorganic Chemistry (BP 104 T)

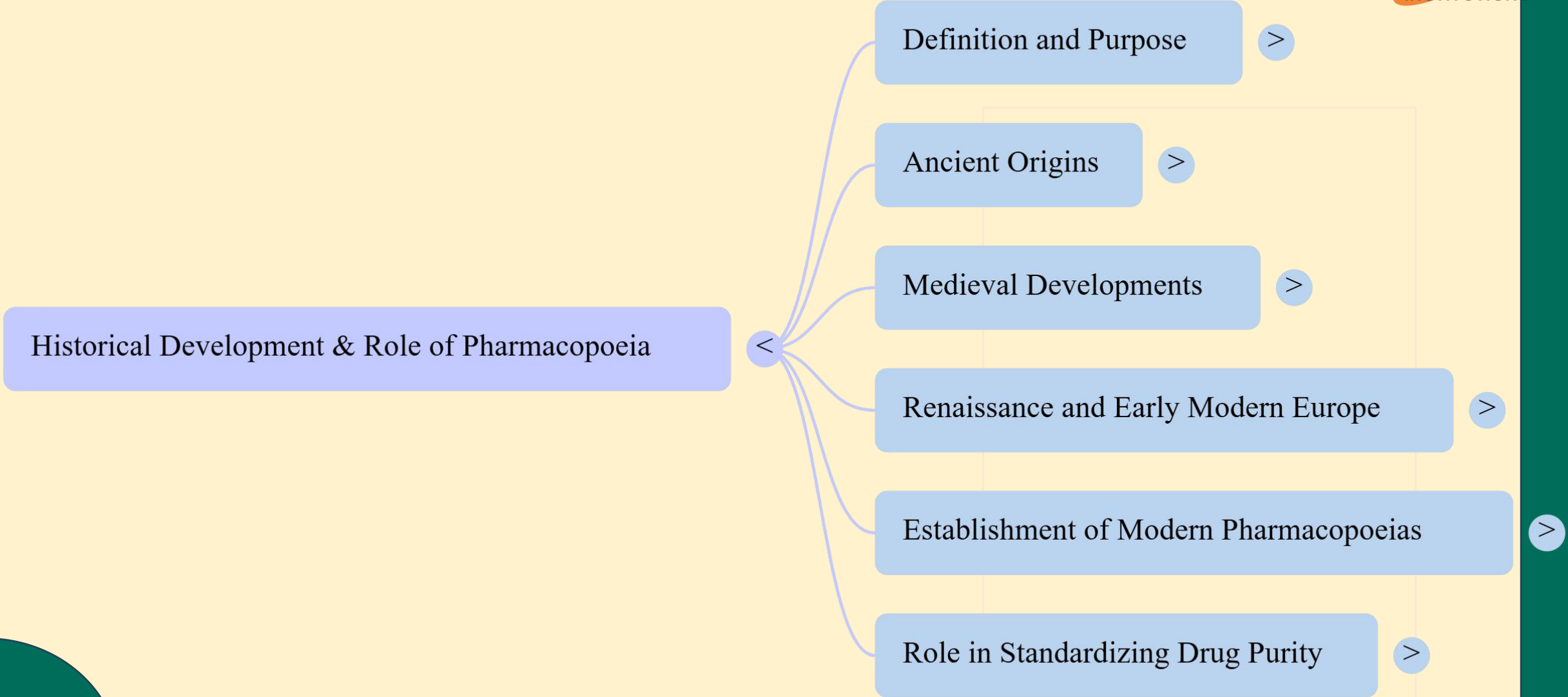
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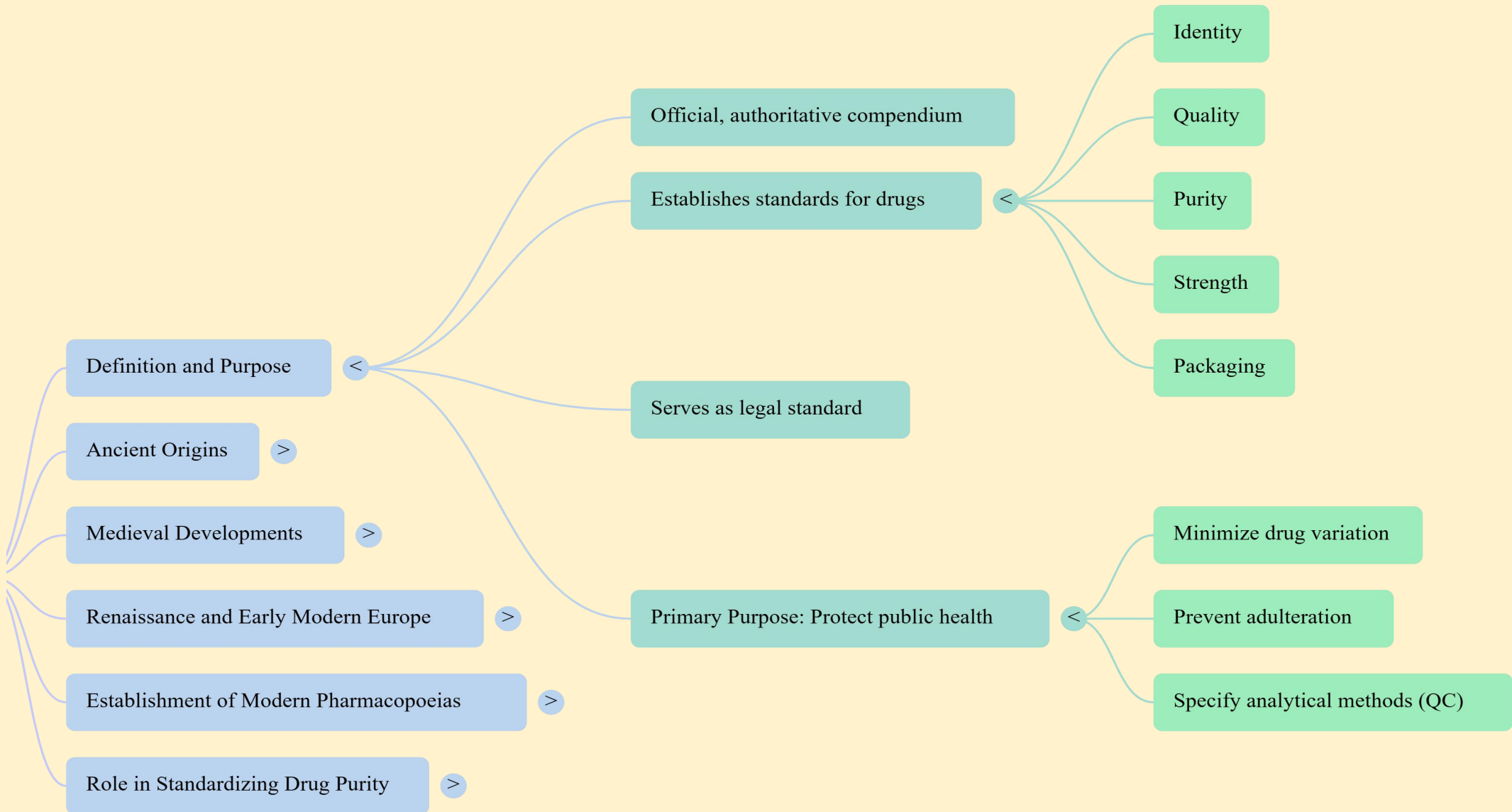
TOPIC: Impurities in pharmaceutical substances (UNIT I)

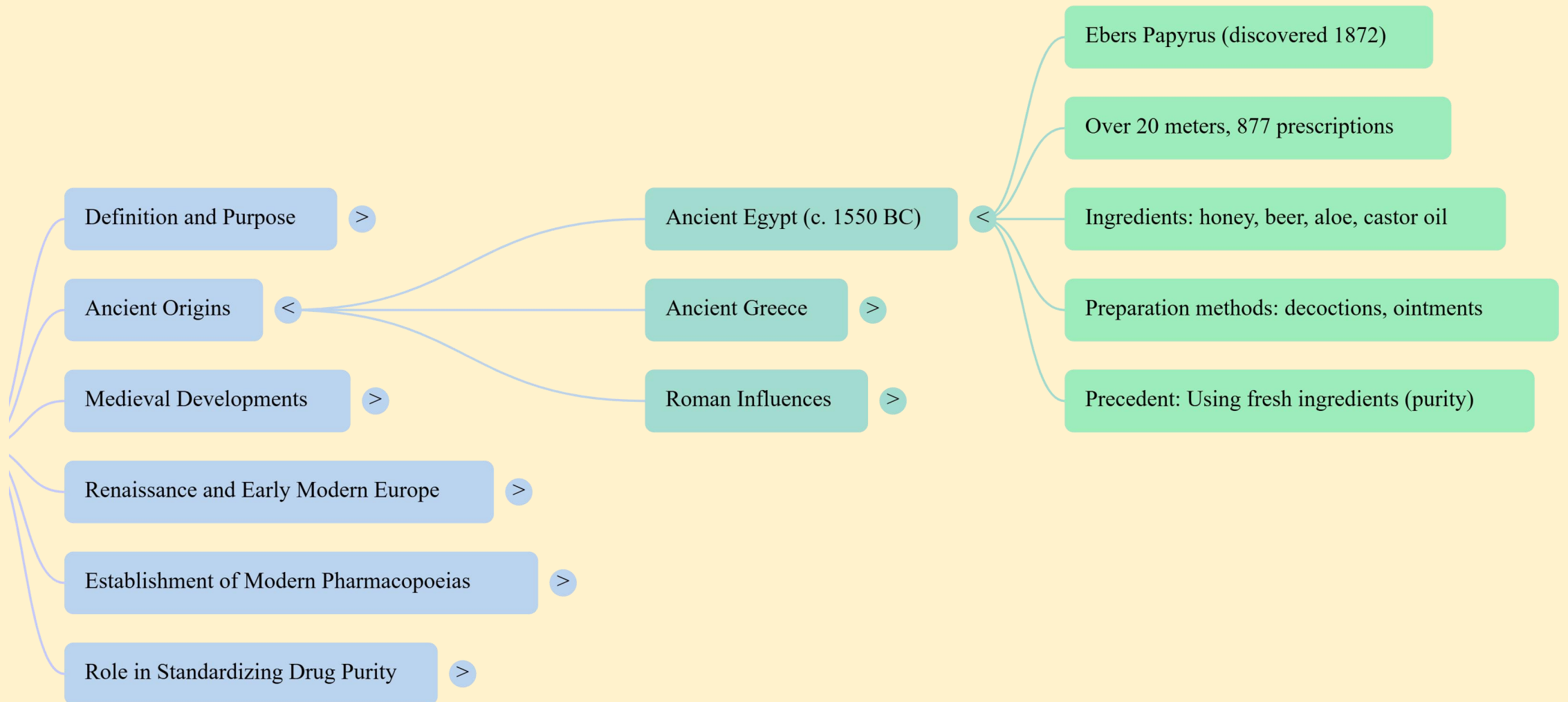
SUB TOPIC: Origins of Pharmacopoeia & Modern Pharmacopoeial Standards

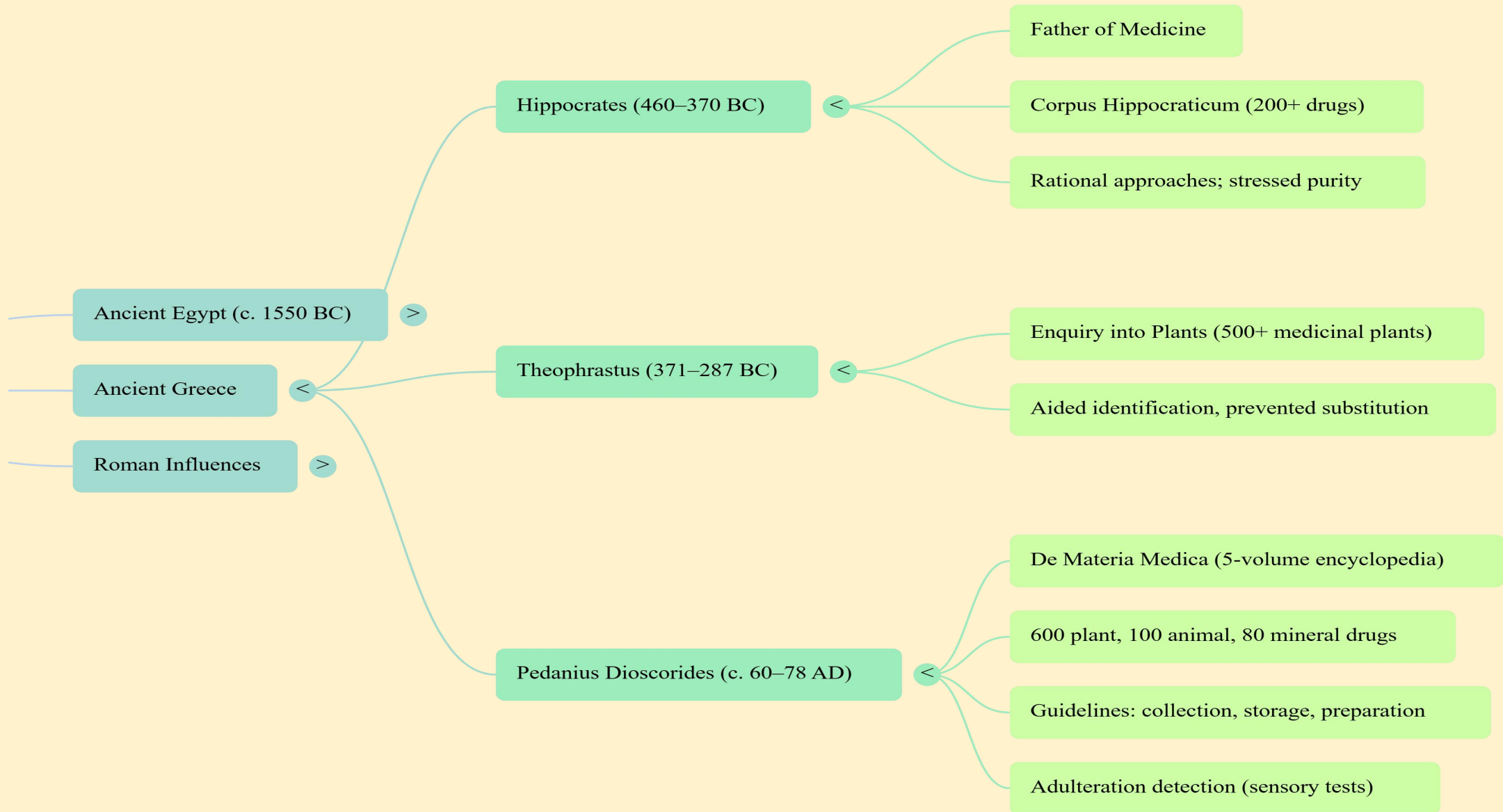
LEARNING OBJECTIVES

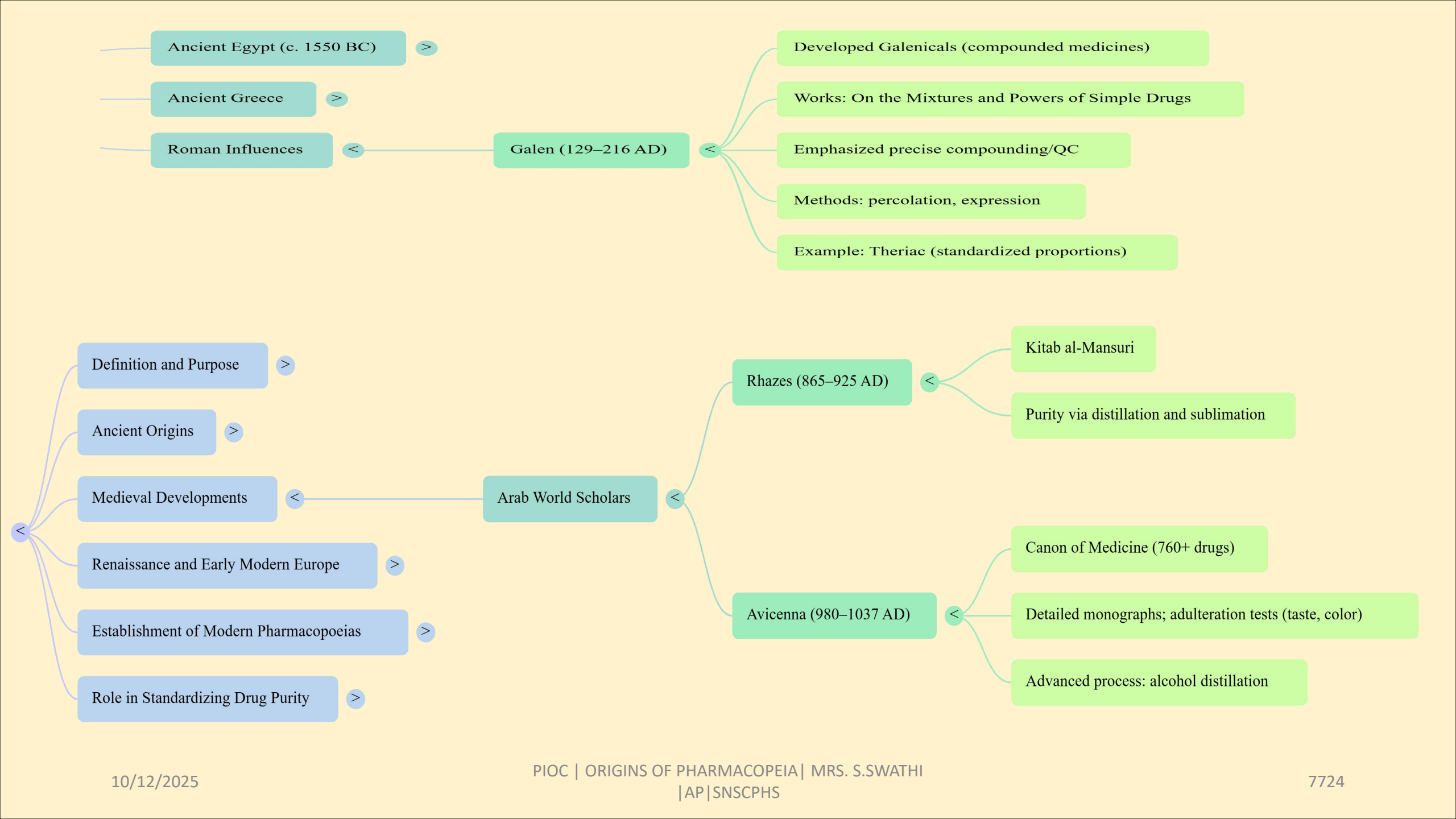
- Understand the historical development of pharmacopoeias from ancient to modern times.
- Identify key milestones and contributors in the evolution of official drug standards.
- Explain the role and structure of major modern pharmacopoeias (e.g., IP, BP, USP, EP).
- Recognize the importance of pharmacopoeial standards in ensuring drug quality, safety, and efficacy.
- Compare and interpret harmonization efforts among global pharmacopoeias for standardization of medicines.

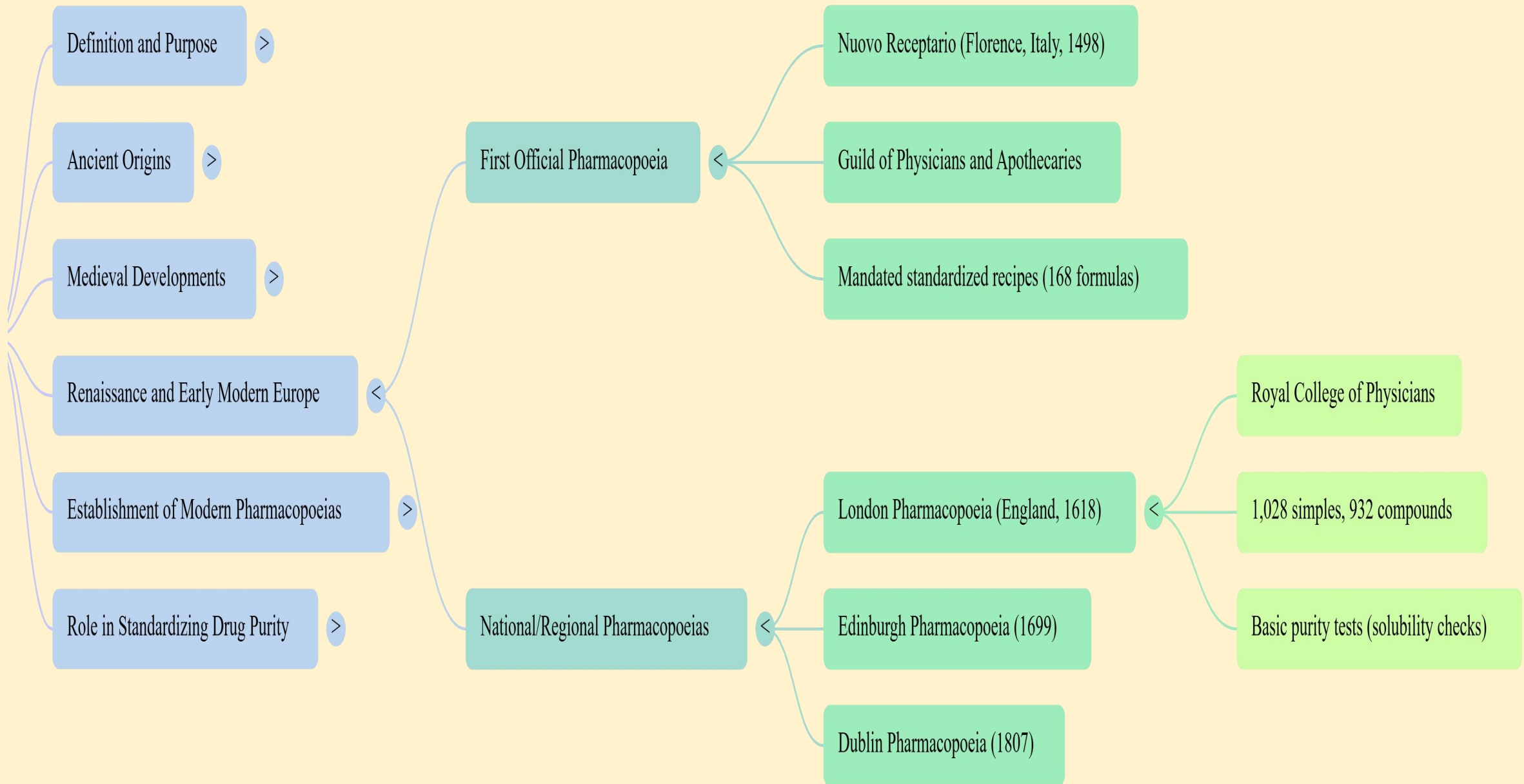


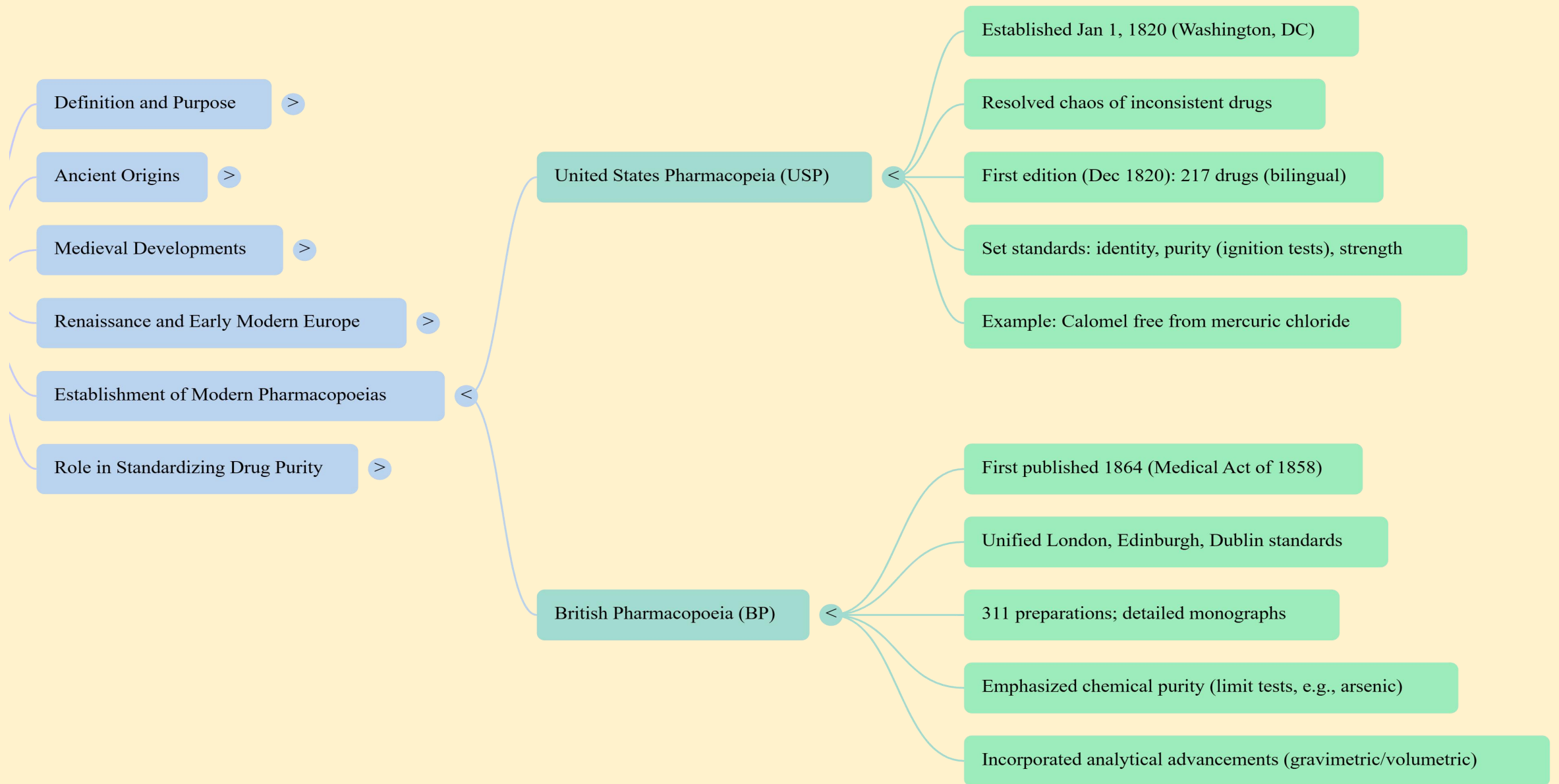


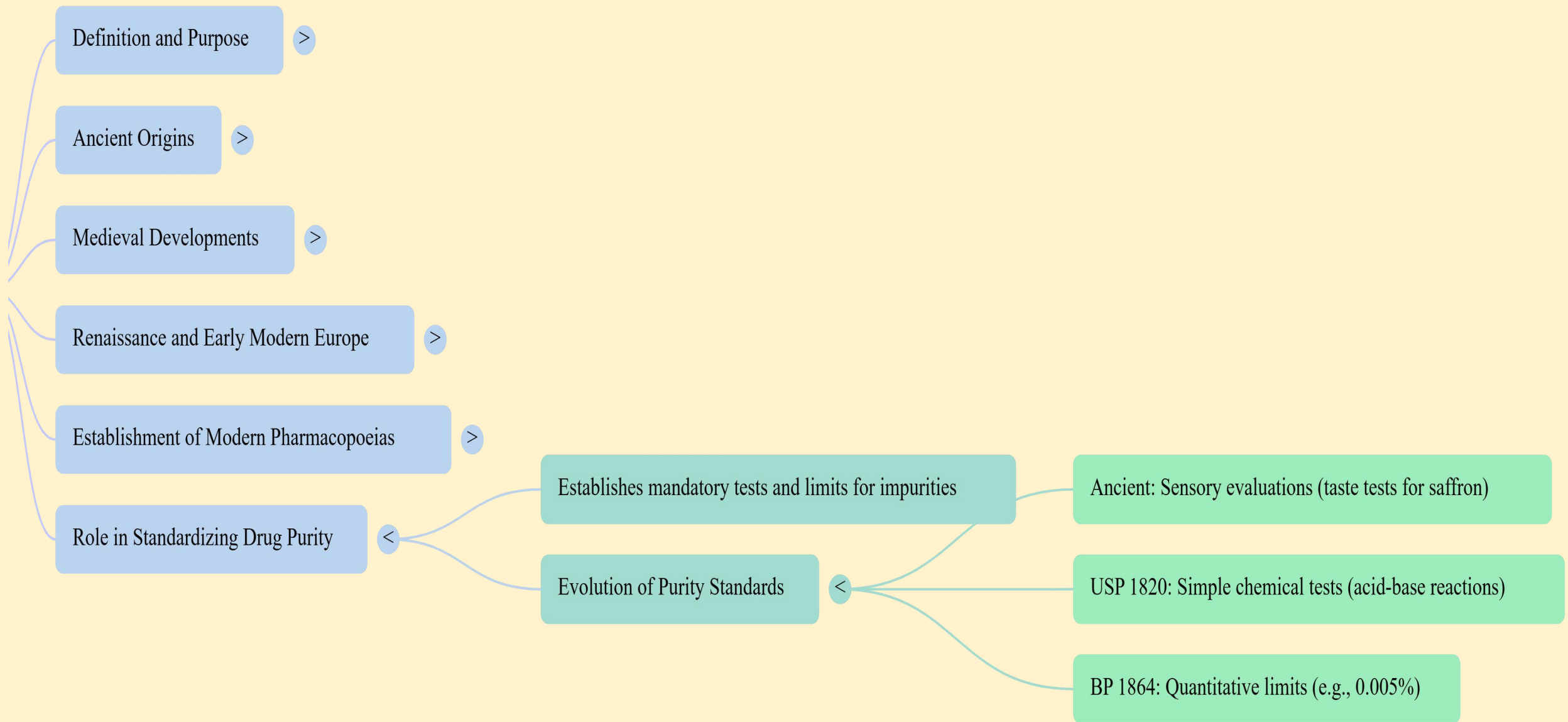






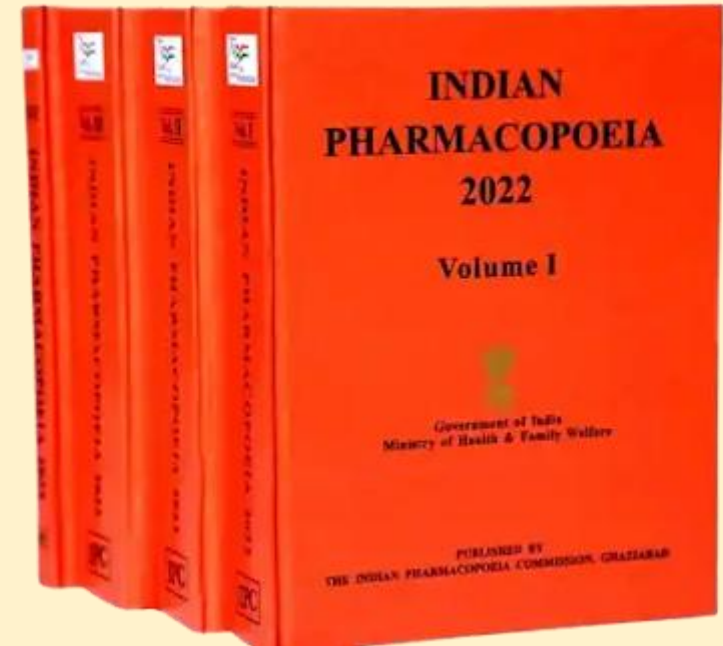






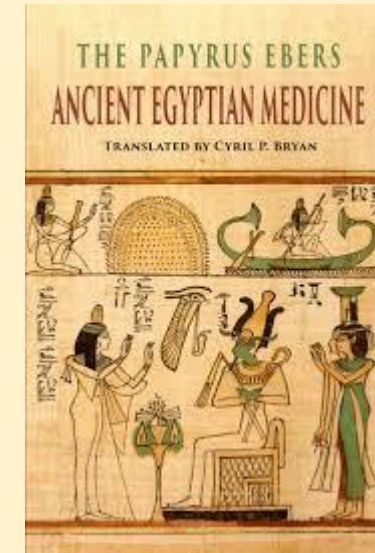
Definition & Purpose

- A pharmacopoeia is an official, authoritative compendium published by a recognized authority, typically a government or professional body, that establishes standards for the identity, quality, purity, strength, and packaging of pharmaceutical substances and medicinal products.
- It serves as a legal standard for ensuring the consistency and safety of drugs, guiding manufacturers, pharmacists, and regulatory bodies in maintaining high quality medicines.
- The primary purpose is to protect public health by minimizing variations in drug composition, preventing adulteration, and specifying analytical methods for quality control.



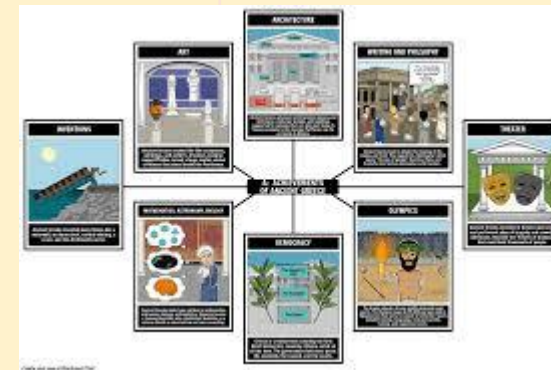
Ancient Egypt (Ebers Papyrus, 1550 BC)

- Ebers Papyrus (1550 BC)
- 20m scroll, 877 remedies for diseases
- Ingredients: Honey, aloe; used fresh for purity
- Example: Pomegranate for worms



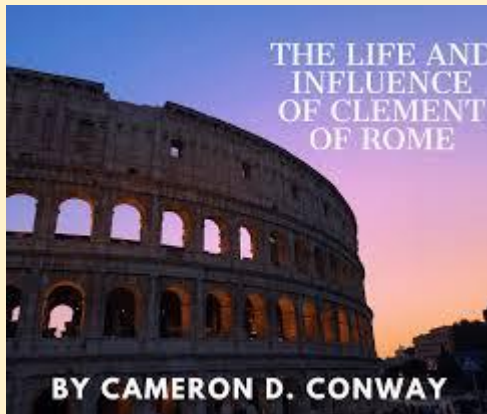
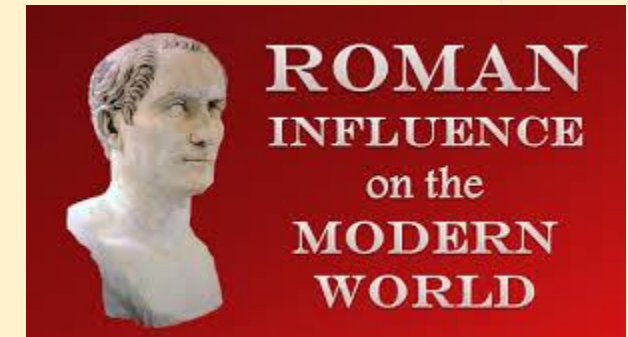
Contributions from Ancient Greece

- **Hippocrates (460–370 BC):** Father of Medicine; rational approaches; >200 drugs in Corpus Hippocraticum; emphasized purity
- **Theophrastus (371–287 BC):** Enquiry into Plants; classified >500 medicinal plants; prevented impure substitutions
- **Dioscorides (60–78 AD):** De Materia Medica; 600+ plants, 100 animals, 80 minerals; guidelines for collection/storage; sensory adulteration tests (e.g., opium from unripe poppies)



Roman Influences

- Galen (129-216 AD): Developed galenicals
- Over 400 remedies with precise compounding
- Introduced percolation, expression; warned of mold
- Theriac: 64-ingredient antidote, standardized proportions



Medieval Developments in the Arab World

- Rhazes (865-925 AD): Kitab al-Mansuri with purity via distillation
- Avicenna (980-1037 AD): Canon with 760 drugs, taste/color impurity tests
- Introduced alcohol distillation, warned of mercury toxicity



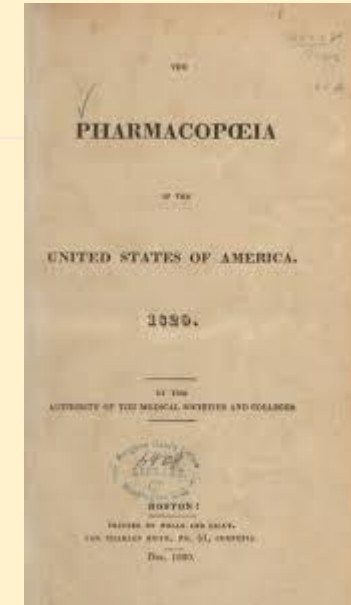
Renaissance and Early Modern Pharmacopoeias in Europe

- Renaissance: Shift to printed pharmacopoeias
- Nuovo Receptario (1498, Florence): 168 standardized recipes
- London Pharmacopoeia (1618): 1,028 simples, 932 compounds
- Regional inconsistencies noted (e.g., Edinburgh 1699, Dublin 1807)



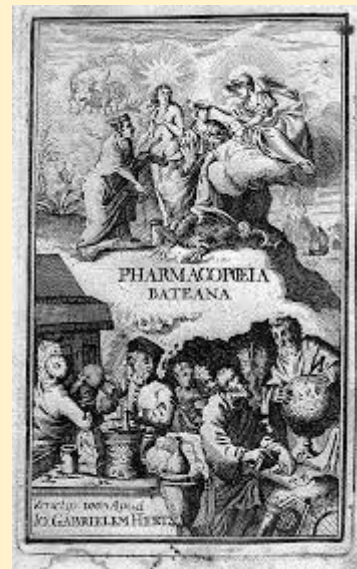
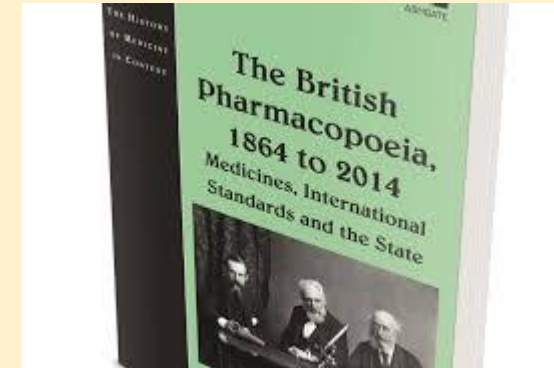
Establishment of the United States Pharmacopeia (1820)

- Founded January 1, 1820, by 11 physicians led by Lyman Spalding
- First edition (Dec 1820): 217 drugs, bilingual (English/Latin)
- Set standards for identity, purity (e.g., ignition tests), strength
- Reduced adulteration risks, e.g., calomel purity with lime water test



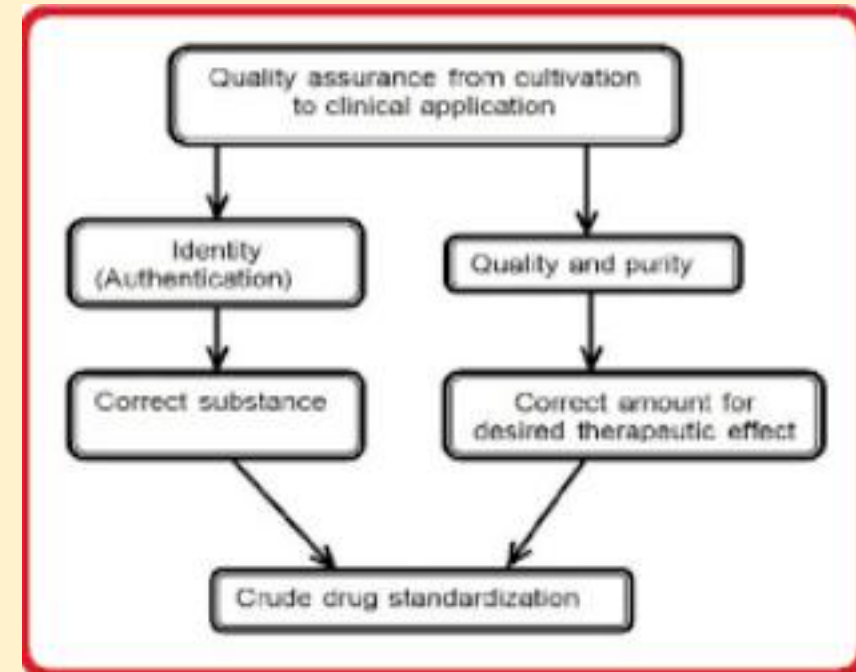
Formation of the British Pharmacopoeia (1864)

- First published in 1864 by General Medical Council
- Unified London, Edinburgh, Dublin standards
- 311 preparations with purity tests for arsenic
- Required $\geq 31.8\%$ hydrochloric acid consistency



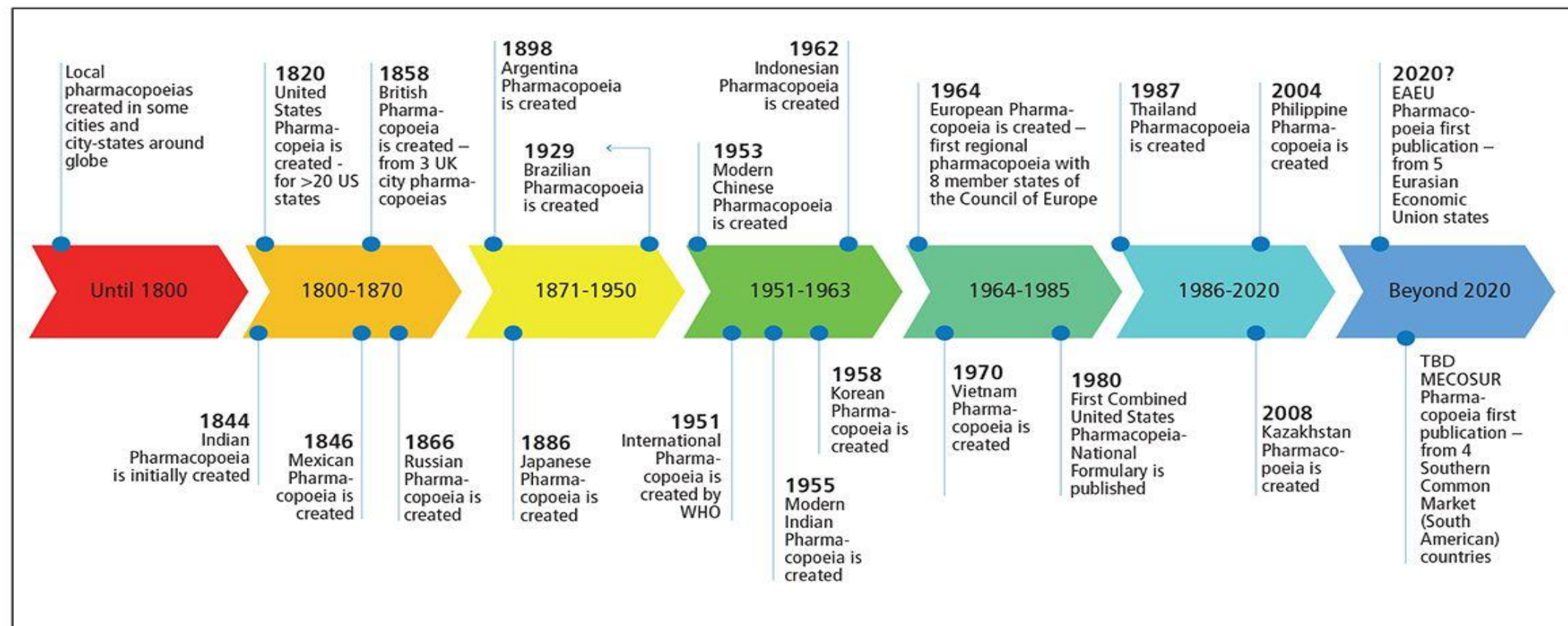
Role in Standardizing Drug Purity

- Pivotal role via mandatory tests and impurity limits
- Evolved from sensory tests (e.g., taste for saffron) to chemical assays (USP 1820)
- BP 1864 added quantitative limits (e.g., $<0.005\%$)



History of Pharmacopoeia:

Figure 1. Timeline indicating the year when many of the pharmacopoeias were created.



Key Takeaways

- **Definition & Purpose:** Pharmacopoeia is an official standard reference that defines the identity, purity, strength, and quality of medicines to ensure public safety and consistency.
- **Ancient Roots:** The concept began in ancient Egypt with the Ebers Papyrus (1550 BC), which detailed over 800 medicinal formulations — an early effort toward standardization.
- **Greek & Roman Contributions:** Works like *De Materia Medica* by Dioscorides and *On the Mixtures of Drugs* by Galen established systematic documentation, purity checks, and compounding methods.
- **Medieval & Renaissance Progress:** Arab scholars (e.g., Avicenna) refined purification techniques, and the first printed pharmacopoeia, *Nuovo Receptario* (1498, Florence), formalized regional drug standards.
- **Modern Foundations:** The United States Pharmacopoeia (1820) and British Pharmacopoeia (1864) introduced national, scientifically tested standards that shaped today's global pharmacopoeial systems.

Textbook References

- 1.Ebers Papyrus (1550 BC, Egypt)** – Among the earliest medical records describing 877 remedies; established primitive purity standards through ingredient freshness.
- 2.Dioscorides' De Materia Medica (60–78 AD, Greece)** – Systematically classified over 600 plant-based drugs and introduced sensory tests for purity and adulteration.
- 3.Galen's Compounded Formulations (129–216 AD, Rome)** – Emphasized precise compounding, storage, and quality control—foundation for modern galenicals.
- 4.Avicenna's Canon of Medicine (980–1037 AD, Arab World)** – Introduced classification of 760 drugs with tests for adulteration and advocated purification by distillation.
- 5.United States Pharmacopoeia (1820) and British Pharmacopoeia (1864)** – Established national standards with defined assays, impurity limits, and analytical tests for consistent drug purity.

Resource References

1. Ebers Papyrus – The Oldest Known Medical Document (1550 BC)

Reference: Nunn, J. F. *Ancient Egyptian Medicine*. University of Oklahoma Press, 1996.

Link: <https://www.britannica.com/topic/Ebers-papyrus>

2. Dioscorides' De Materia Medica – Foundation of Western Pharmacopoeia

Reference: Riddle, J. M. *Dioscorides on Pharmacy and Medicine*. University of Texas Press, 1985.

Link: https://www.nlm.nih.gov/exhibition/historicalanatomies/dioscorides_home.html

3. Galen's Contributions to Standardized Preparations

Reference: Smith, W. D. "Galen and the Origins of Experimental Pharmacology." *Journal of the History of Medicine*, 2002.

Link: <https://www.sciencedirect.com/science/article/pii/S0039359202000094>

4. Avicenna's Canon of Medicine – Influence on Drug Purity Standards

Reference: Pormann, P. E., & Savage-Smith, E. *Medieval Islamic Medicine*. Edinburgh University Press, 2007.

Link: <https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/avicenna>

5. Establishment of the British and United States Pharmacopoeias

Reference: Anderson, S. "Making Medicines: A Brief History of Pharmacy and Pharmaceuticals." *Pharmaceutical Press*, 2005.

Link: <https://www.pharmpress.com/product/9780853695976/making-medicineshttps://nhm.gov.in>

