SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai
Approved by Pharmacy Council of India, New Delhi.
Coimbatore -641035

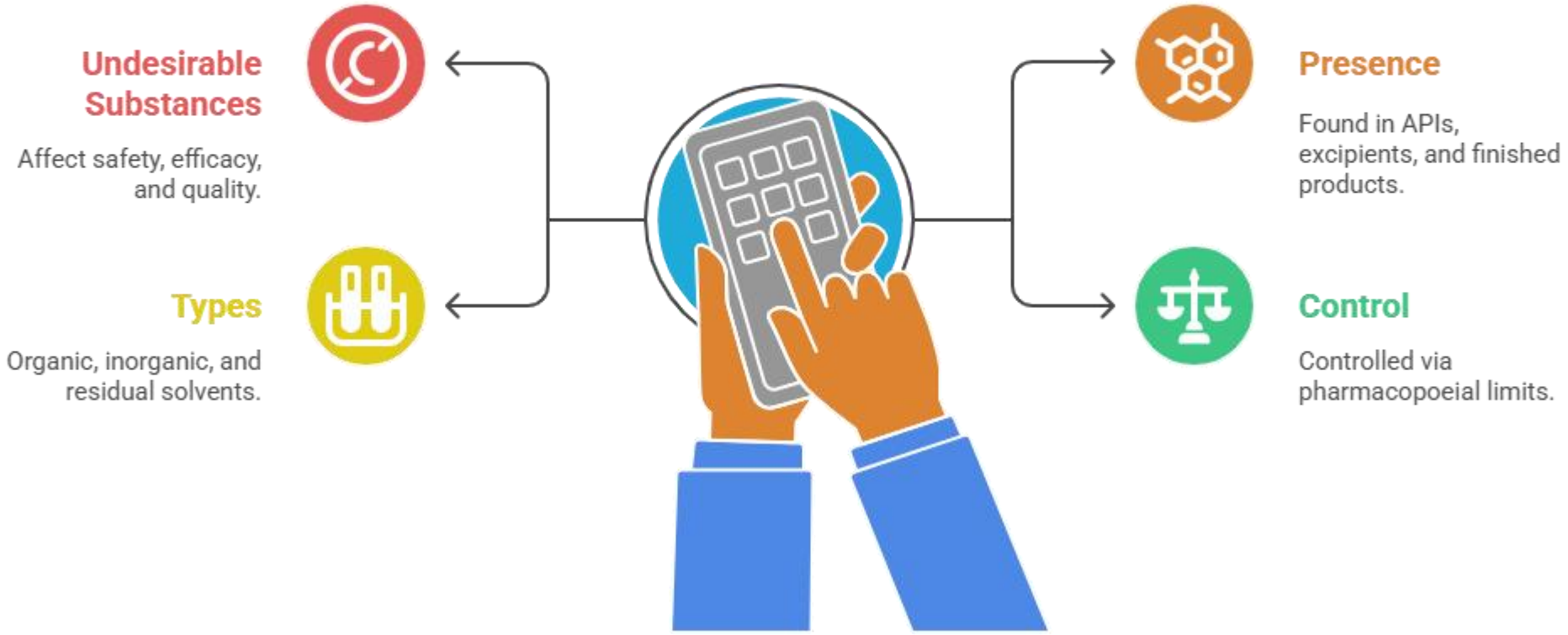
COURSE NAME : Pharmaceutical Inorganic Chemistry (BP 104 T)

I YEAR / I SEM

TOPIC: Sources of Impurities in Pharmaceuticals (UNIT I)

(Identifying contaminants in APIs and excipients)

Impurities


Undesirable Substances
Affect safety, efficacy, and quality.
Types
Organic, inorganic, and residual solvents.
Presence
Found in APIs, excipients, and finished products.
Control
Controlled via pharmacopoeial limits.
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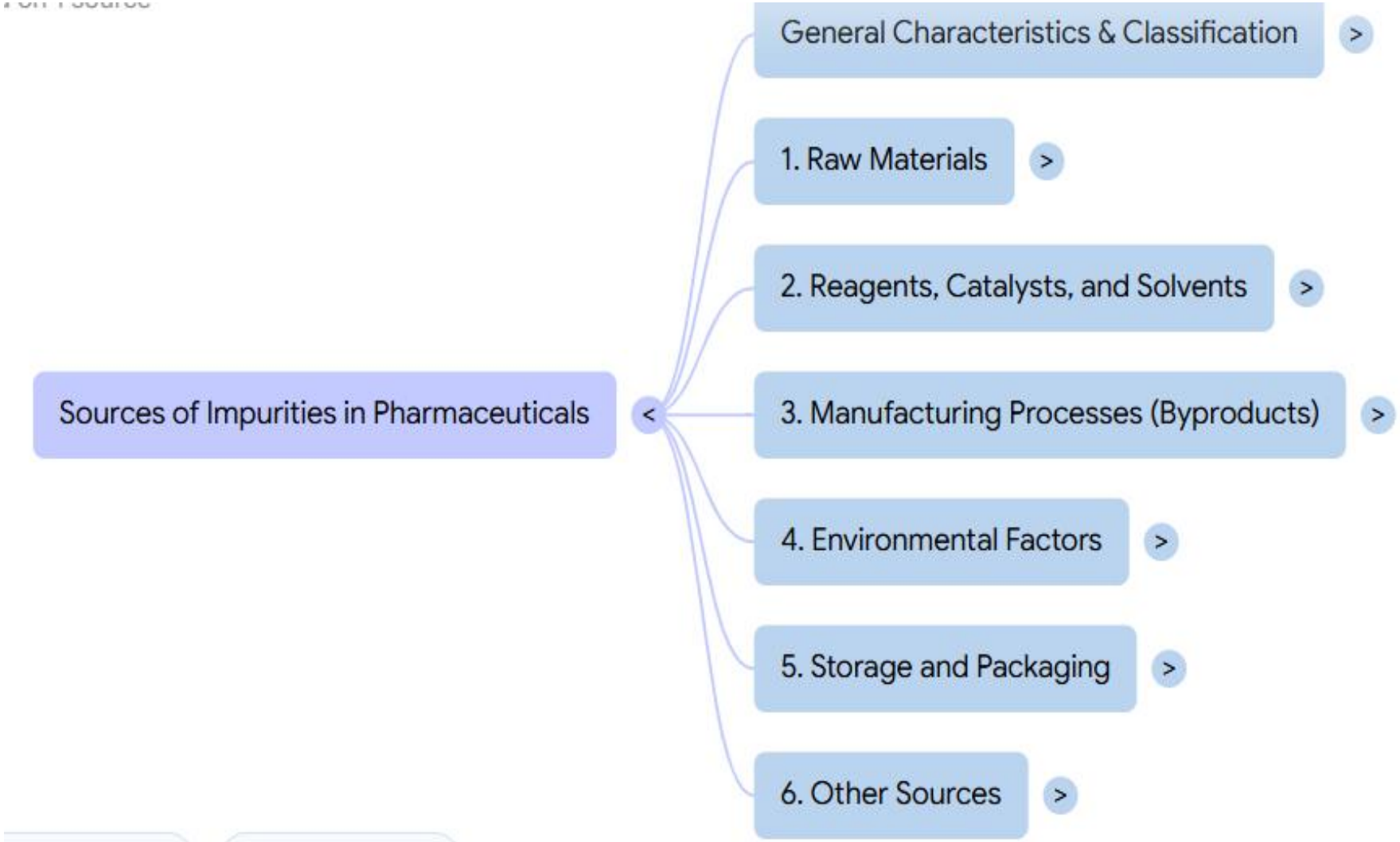
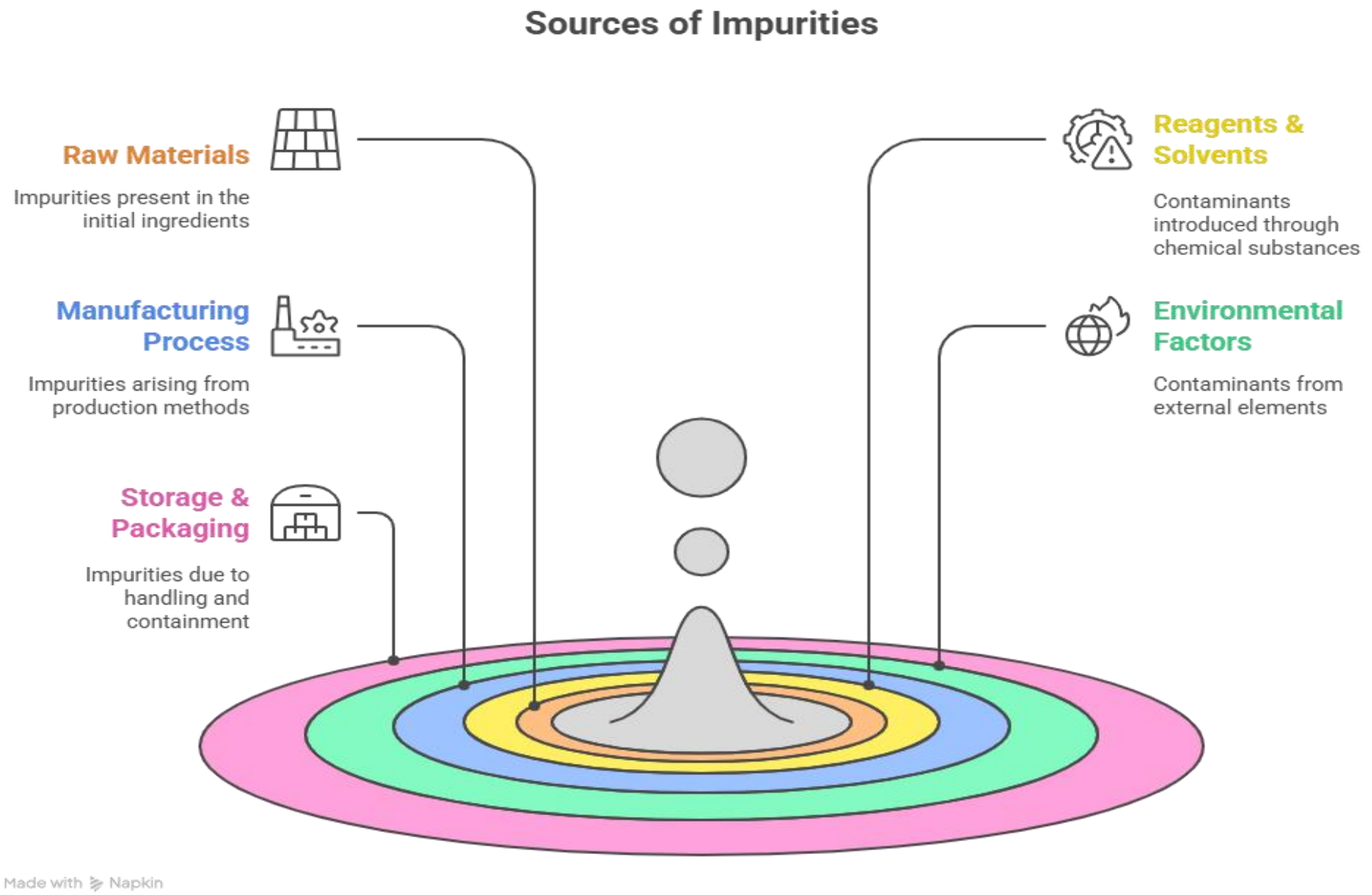

Sources of Impurities in Pharmaceuticals
General Characteristics & Classification
1. Raw Materials
2. Reagents, Catalysts, and Solvents
3. Manufacturing Processes (Byproducts)
4. Environmental Factors
5. Storage and Packaging
6. Other Sources
Good content
Bad content

Classification of Impurity Sources



1. Raw Material Contaminants

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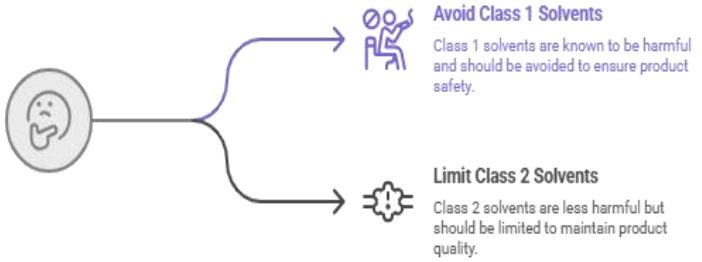
Sources of Raw Material Contaminants

2. Reagents, Catalysts & Solvents

How to manage residual solvents in pharmaceutical products?



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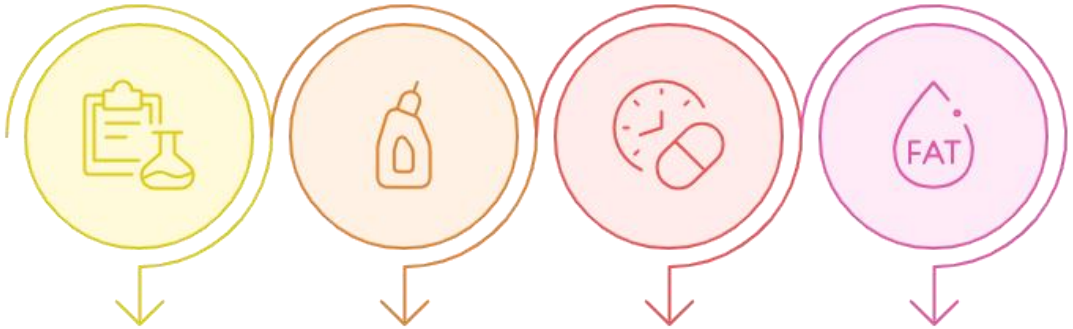
Impurities in Pharmaceuticals



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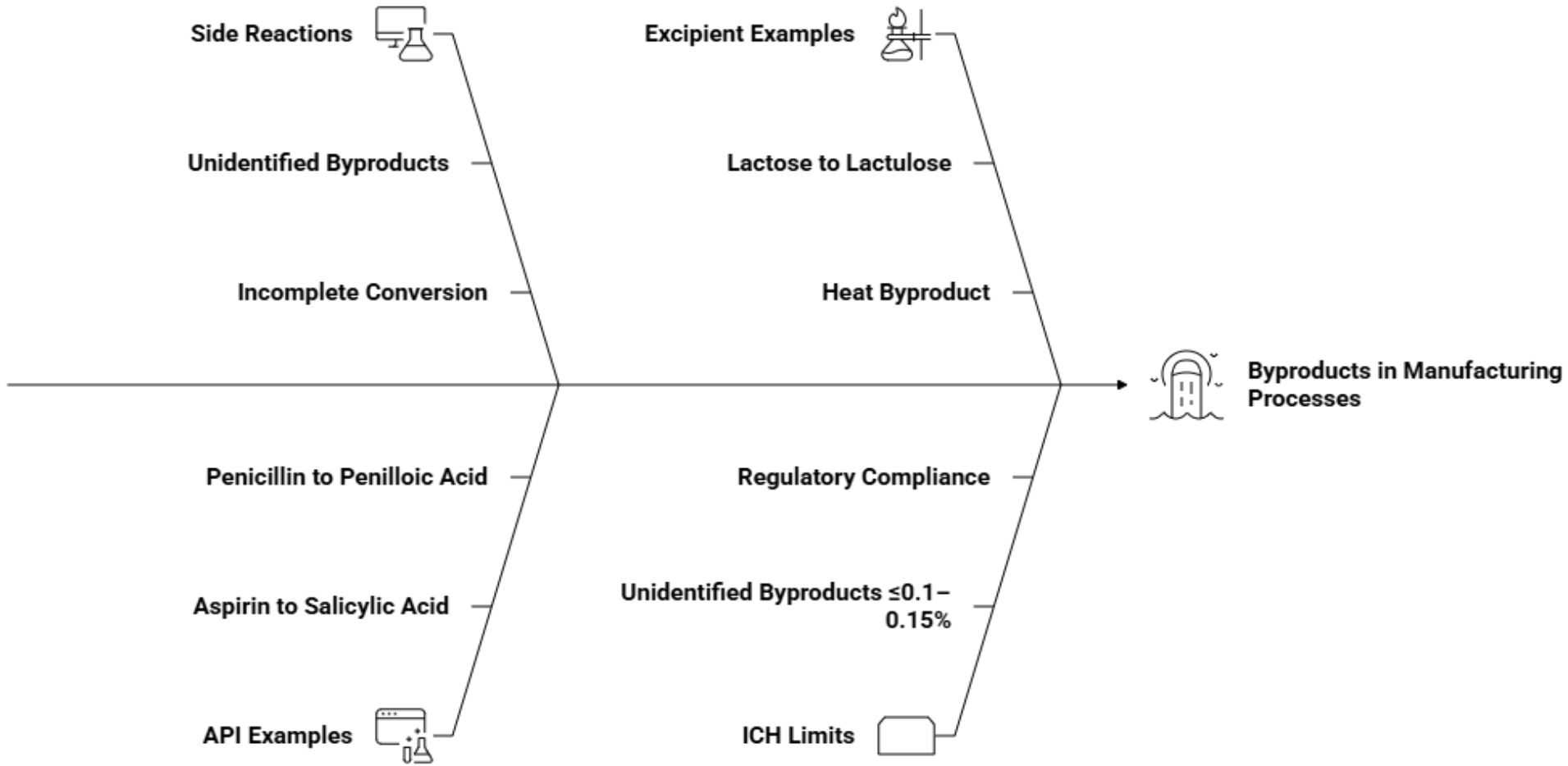
3. Manufacturing Process Byproducts

Analyzing Byproducts in Manufacturing Processes



4. Environmental Factors

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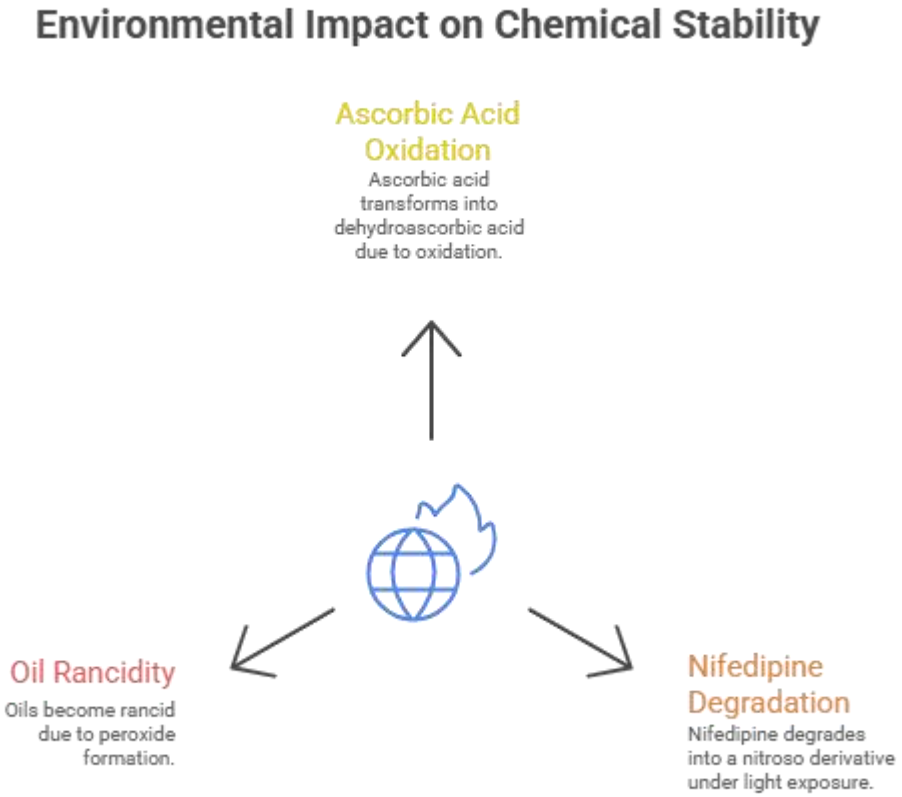

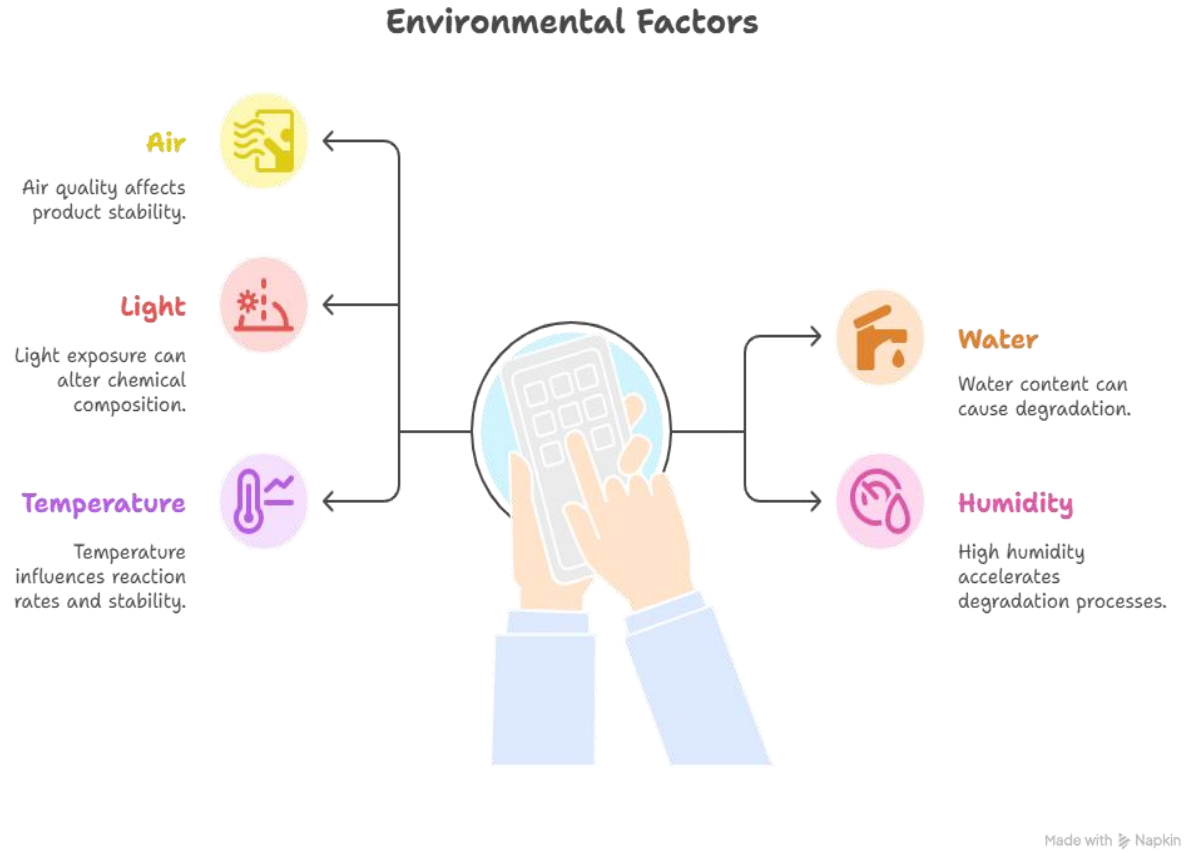

Harmonization Efforts by the International Council for Harmonisation (ICH)

ICH Formation and Mission

1. **Founding in Brussels**
   ICH was established in 1990 in Brussels.
2. **Member Organizations**
   EMA, MHLW, FDA, EFPIA, JPMA, and PhRMA joined as members.
3. **Observer Organizations**
   WHO, Canada, Brazil, and China participated as observers.
4. **Mission Statement**
   ICH aimed to harmonize technical requirements and reduce costs.
5. **Guideline Development**
   Over 60 guidelines were developed in 25+ years.

ICH's Strategic Goals

Eliminating Redundant Testing

Streamlining processes to avoid unnecessary repetition

Enabling Mutual Recognition of Data

Fostering trust and acceptance of data across regions

Promoting Science- & Risk-Based Quality Control

Ensuring quality through scientific rigor and risk assessment

Supporting Global Adoption via Training

Facilitating widespread understanding and implementation

Key ICH Impurity Guidelines

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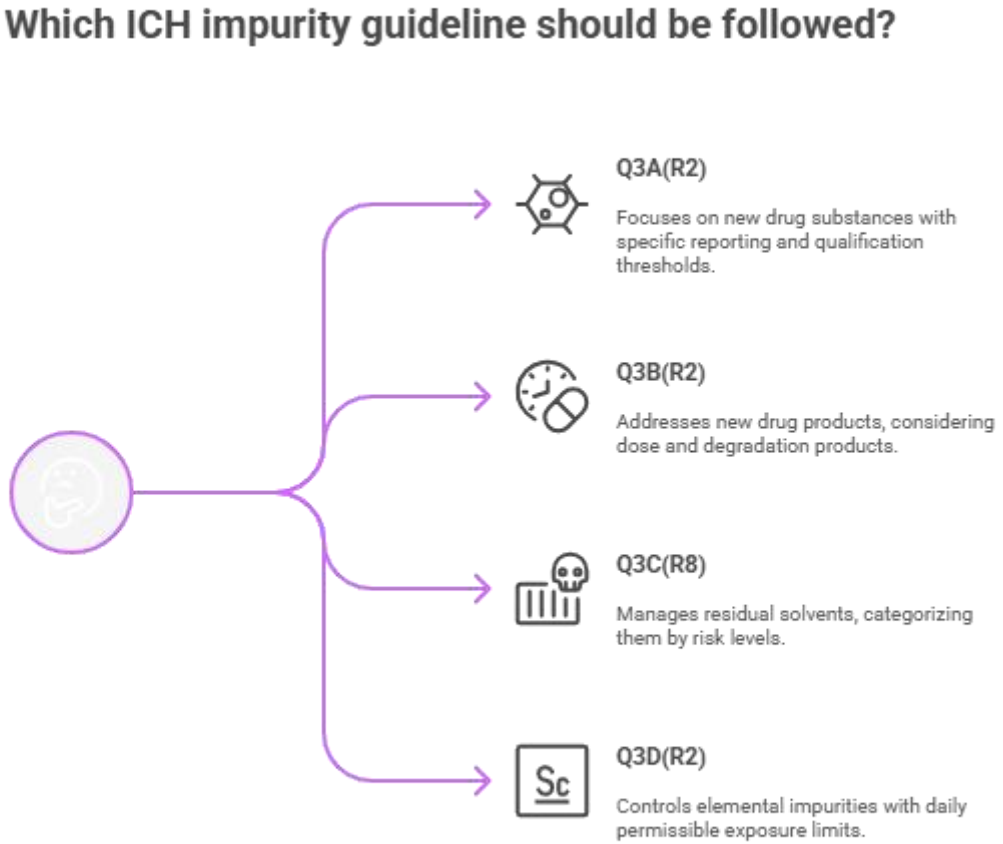
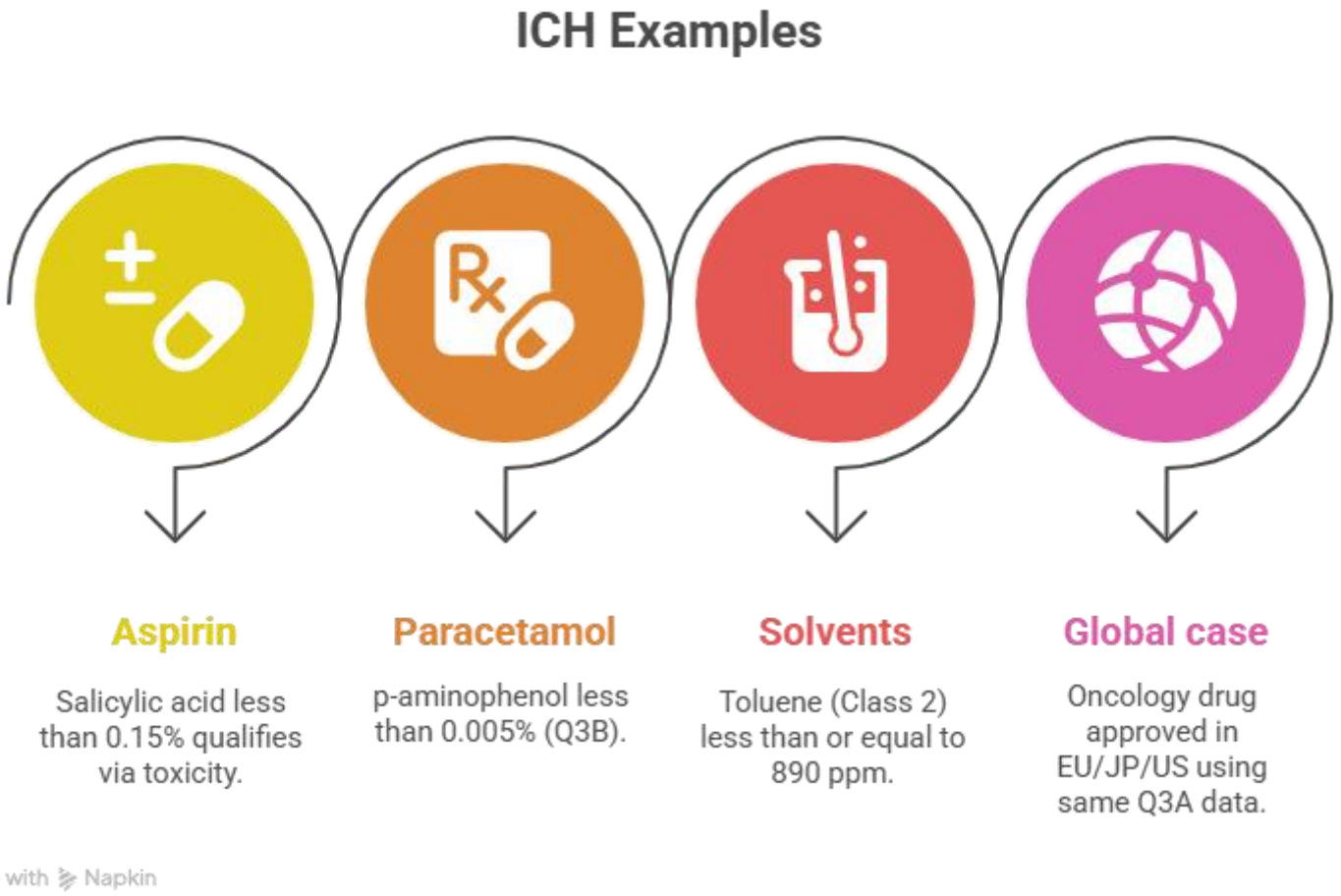


ICH Examples



Global Impact of WHO & ICH

Consistency

Uniform impurity limits ensure reliable quality worldwide.

Economic

Saves billions in testing and clinical trials.

Examples

Generic ARVs, herbal medicines, and injectables benefit.

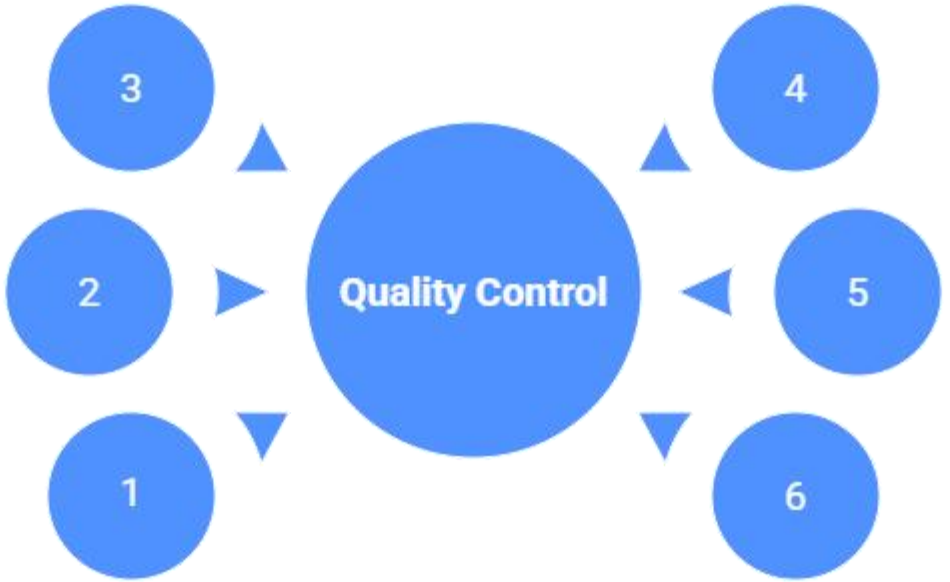
Safety

Standardized toxic thresholds protect public health.

Regulatory

Faster approvals are achieved through data sharing.

Comprehensive Quality Control Parameters



Assay

Techniques to determine the substance's concentration

Purity

Measures to ensure the substance is free from contaminants

Identification

Methods to confirm the substance's identity

Inorganic Limit Tests

Tests to detect and quantify inorganic impurities

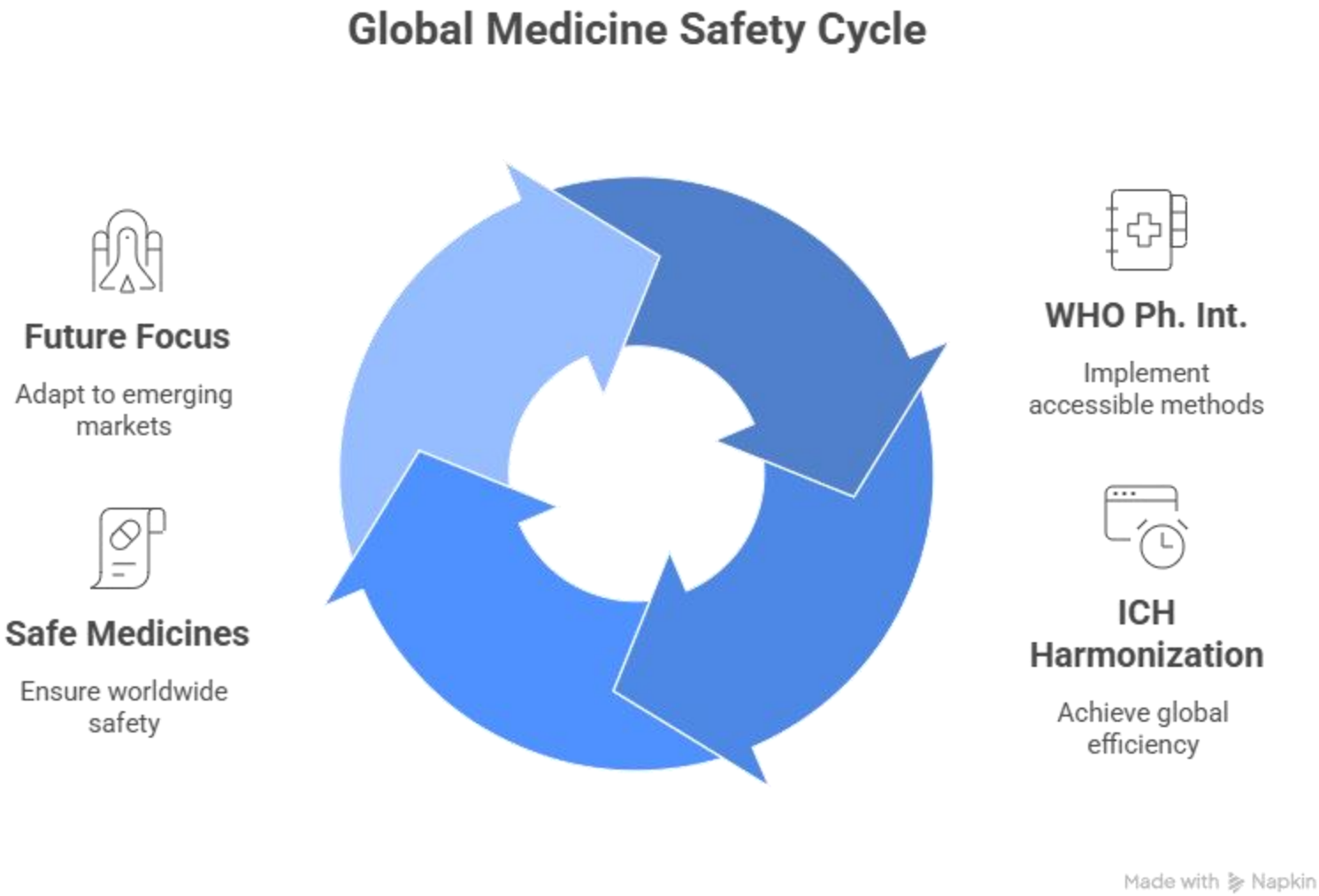
Other Parameters

Additional tests for pH, microbial limits, and endotoxins

Advanced Tests

Sophisticated methods for related substances and dissolution

SUMMARY AND TAKEWAYS



1: When was the International Council for Harmonisation (ICH) founded, and which three regions were its original regulatory members?

A) 1951; WHO, Europe, Japan

B) 1990; EU (EMA), Japan (MHLW), USA (FDA)

International Council for Harmonisation (ICH)

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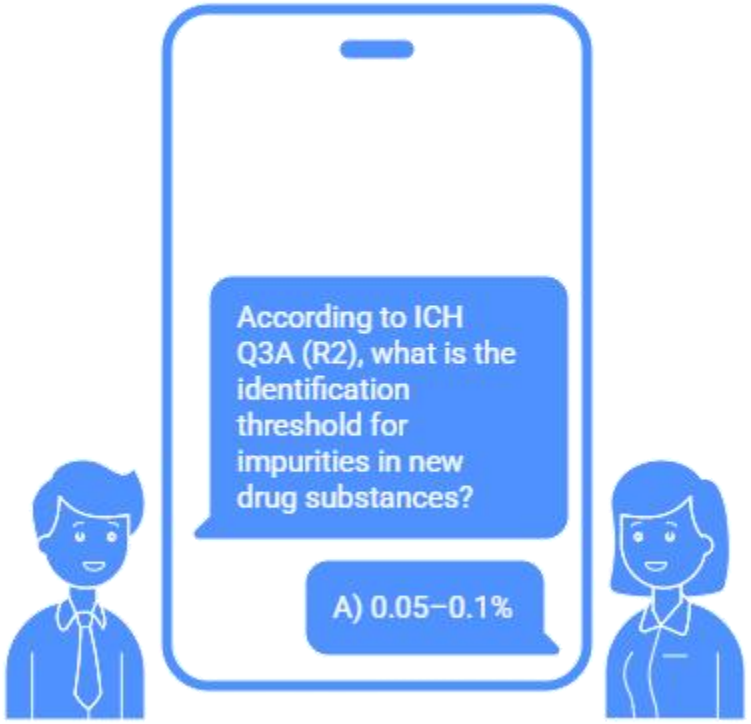
2: According to ICH Q3A (R2), what is the identification threshold for impurities in new drug substances?

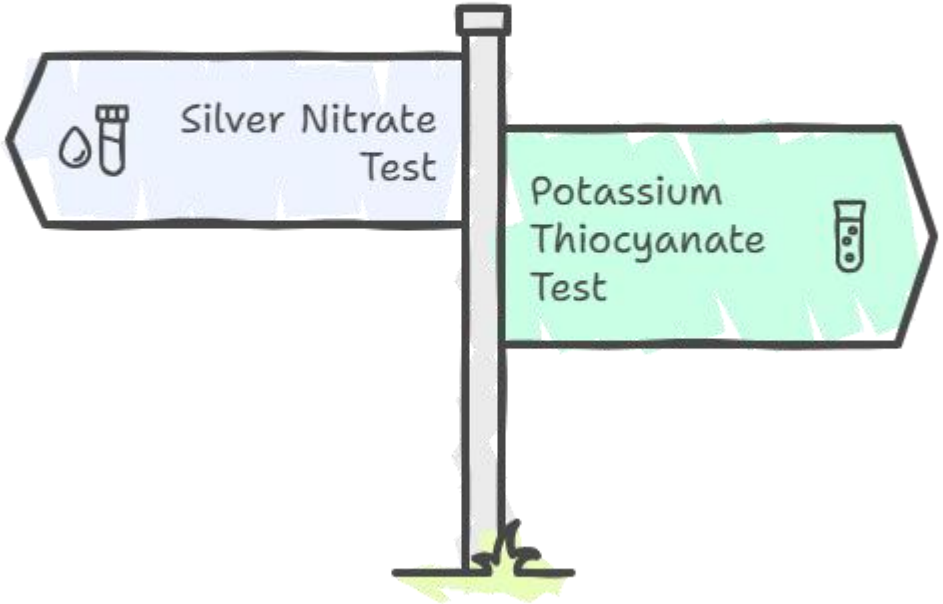
A) 0.05–0.1%

B) 0.1–0.2%

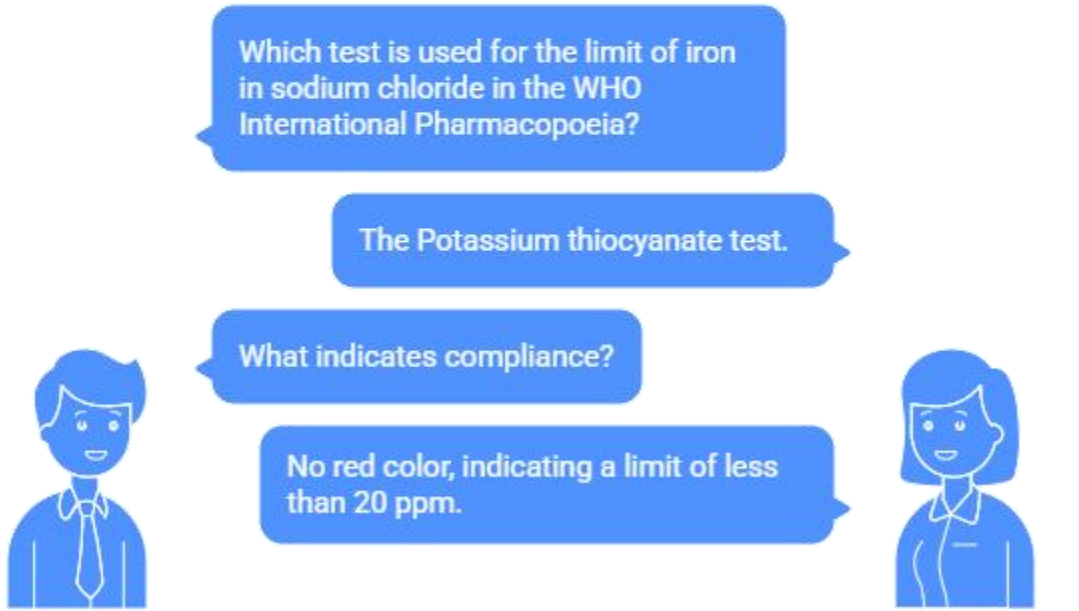
ICH Q3A Identification Threshold



Which test to use for iron limit in sodium chloride?



Limit of Iron in Sodium Chloride



4: Which ICH guideline classifies residual solvents into Class 1 (to avoid), Class 2 (limit), and Class 3 (low toxicity), with benzene limited to <2 ppm?

A) Q3D (R2)

B) Q3C (R8)

Which ICH guideline classifies residual solvents?

Q3D (R2)

Focuses on elemental impurities, not residual solvents.

Q3C (R8)

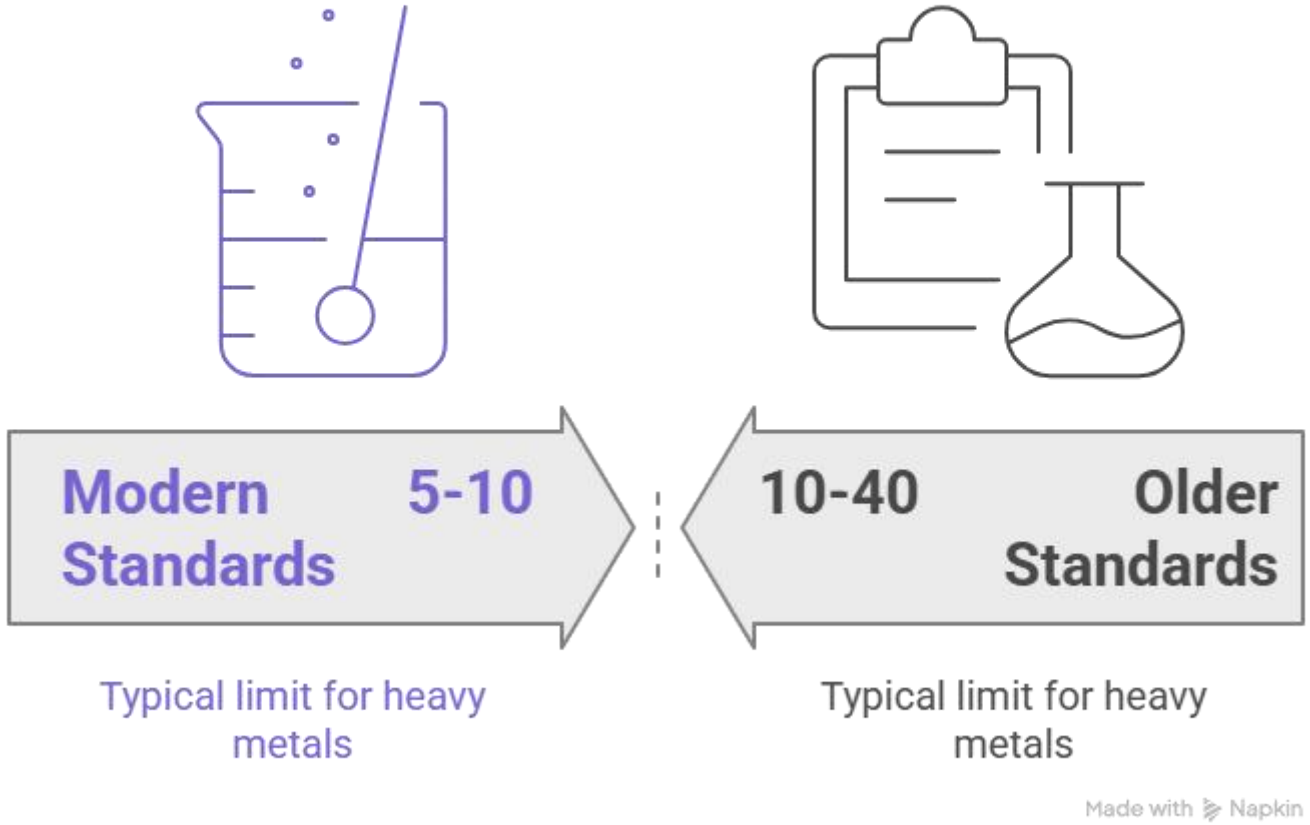
Classifies residual solvents into three classes with specific limits.

5.In modern pharmacopoeial standards, what is the typical limit for heavy metals using the hydrogen sulphide precipitation method, as seen in magnesium sulphate?

A) 5–10 ppm

B) 10–40 ppm

Heavy Metal Limit (ppm)



REFERENCES

🕮Textbook References

1.WHO International Pharmacopoeia, 11th Edition (2022) – Cited in Session 2.pdf, p. 2.

2.ICH Guideline Q3A(R2): Impurities in New Drug Substances – Cited in Session 2.pdf, p. 3.

3.ICH Guideline Q3B(R2): Impurities in New Drug Products – Cited in Session 2.pdf, p. 3.

4.ICH Guideline Q3C(R8): Residual Solvents – Cited in Session 2.pdf, p. 3.

5.ICH Guideline Q3D(R2): Elemental Impurities – Cited in Session 2.pdf, p. 3–4.


Thank You