

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES



UNIT 1

COURSE NAME: QCSH

TOPIC: EVALUTION OF CRUDE DRUG INTENDED FOR INTERNAL USE

CASE STUDY PUZZLE 1: The Bitter Senna Scandal

Topic: Macroscopic & Organoleptic Evaluation

Scenario: A herbal laxative labeled “Senna Leaf Powder” is recalled after patients report **no effect**.

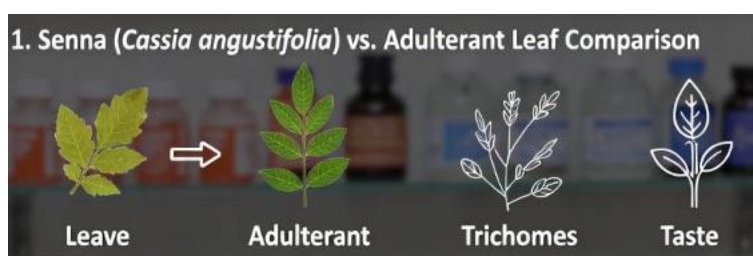
- **Label claim:** *Cassia angustifolia*
- **Organoleptic:** Sweet taste, no bitterness
- **Macroscopy:** Broken pods mixed with leaves

Puzzle Questions:

1. What **adulterant** is likely present?
2. How to **confirm macroscopically**?
3. Why **no laxative effect**?

Answer Key:

1. **Cassia auriculata (Tanner’s Cassia)** — pods + sweet taste.
2. **Senna:** Lanceolate leaflets, mucilage hairs; **Adulterant:** Obovate leaflets, no hairs.
3. **Sennosides absent** → no anthraquinone laxation.



CASE STUDY PUZZLE 2: The Moldy Ginger Tea

Topic: Microbial Limit Test & Aflatoxin

Scenario: A ginger tea bag causes **liver enzyme elevation** in 12 consumers.

- **Total fungal count:** 1.2×10^6 CFU/g (IP limit: $\leq 10^4$)
- **Aflatoxin B1:** 35 ppb (WHO limit: ≤ 5 ppb)
- **Storage:** Damp warehouse

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Puzzle Questions:

1. Which **test failed**?
2. Calculate **% over limit** for aflatoxin.
3. Preventive measure?

Answer Key:

1. **Microbial Limit (fungi) + Aflatoxin assay (TLC/HPTLC).**
2. $\% \text{ over limit} = \frac{35-5}{5} \times 100 = 600\%$
3. **Dry at <60°C, store <60% RH, use silica gel sachets.**



CASE STUDY PUZZLE 3: The Weak Ashwagandha Capsules

Topic: Assay of Marker Compound (Withanolides)

Scenario: Ashwagandha capsules (500 mg) claim “5% withanolides”.

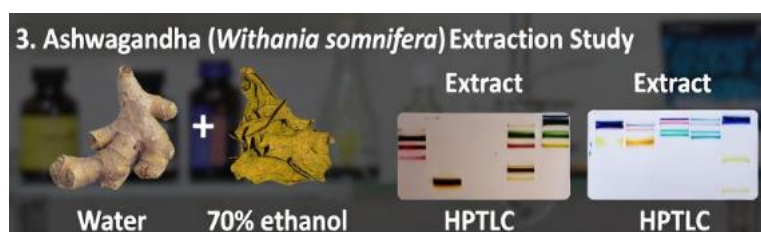
- **HPTLC assay:** 0.8% w/w
- **Extraction solvent used:** Water (instead of 70% ethanol)
- **Patient feedback:** No stress relief

Puzzle Questions:

1. Why **low withanolides**?
2. Calculate **actual vs claimed**.
3. Correct extraction method?

Answer Key:

1. **Water insoluble withanolides** → poor extraction.
2. $\text{Actual} = 0.8\% \times 500 = 4 \text{ mg/caps}$ vs 25 mg claimed
3. **70% ethanol, 60°C, 2 hr reflux.**



CASE STUDY PUZZLE 4: The Heavy Metal Turmeric

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Topic: Heavy Metal Limit Test (AAS/ICP-MS)

Scenario: Turmeric powder causes **abdominal pain, anemia**.

- **Lead (Pb):** 18 ppm (IP limit: ≤ 10 ppm)
- **Source:** Grown near battery recycling plant
- **Color:** Unusually bright yellow

Puzzle Questions:

1. Likely **cause of bright color**?
2. Calculate **safe daily intake** if 1 g/day consumed.
3. Remediation?

Answer Key:

1. **Lead chromate (PbCrO_4)** — illegal yellow pigment.
2. Daily Pb = $18 \mu\text{g/g} \times 1 \text{ g} = 18 \mu\text{g} > \text{WHO PTDI } 3.57 \mu\text{g/kg} \times 60 \text{ kg} = 214 \mu\text{g}$
→ **Toxic**.
3. **Soil testing, chelation (EDTA), switch source.**



CASE STUDY PUZZLE 5: The Fluorescent Licorice Root

Topic: Foreign Matter & Fluorescence Analysis

Scenario: Licorice root powder (for peptic ulcer) shows **blue fluorescence** under UV 365 nm.

- **Foreign matter:** 8% w/w (IP limit: $\leq 2\%$)
- **Microscopy:** Sand particles + synthetic fiber
- **Fluorescence:** Bright blue (not characteristic dull brown)

Puzzle Questions:

1. What causes **blue fluorescence**?
2. How to **quantify foreign matter**?
3. Biological risk?

Answer Key:

1. **Optical brightener** from synthetic packaging fiber.
2. % foreign matter = $\frac{\text{weight after sieving}}{\text{initial weight}} \times 100$
3. **GI irritation, perforation risk from sand.**

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