PHARM.D • YEAR 1

Pharmaceutical Inorganic Chemistry

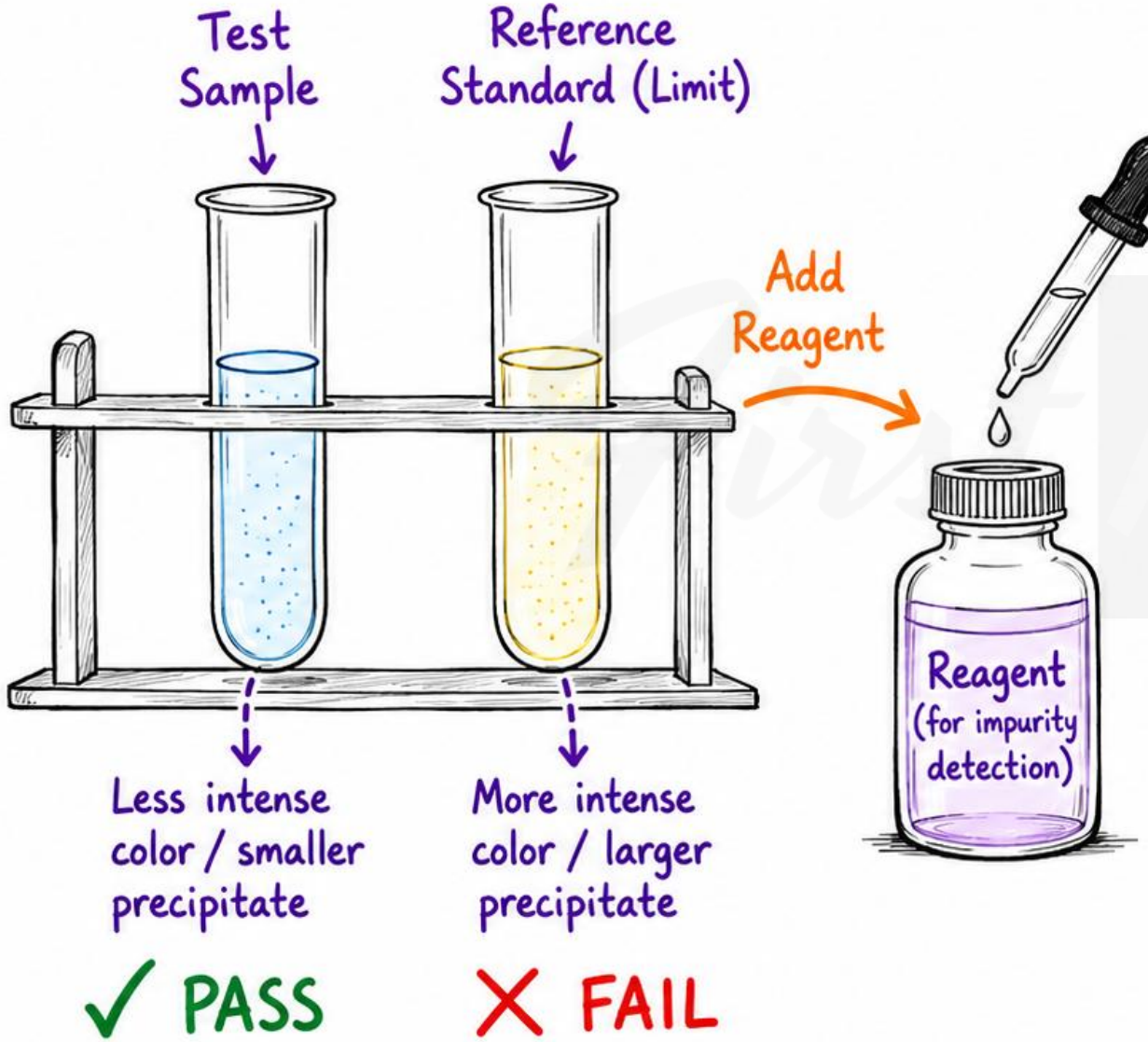
CHAPTER 10

Limit Tests

PPT CHAPTER COVER



Limit Tests: Purpose and Pass-Fail Logic



1 Purpose:

Confirm an impurity or substance is present below a predefined acceptable limit to ensure quality, safety, and efficacy.

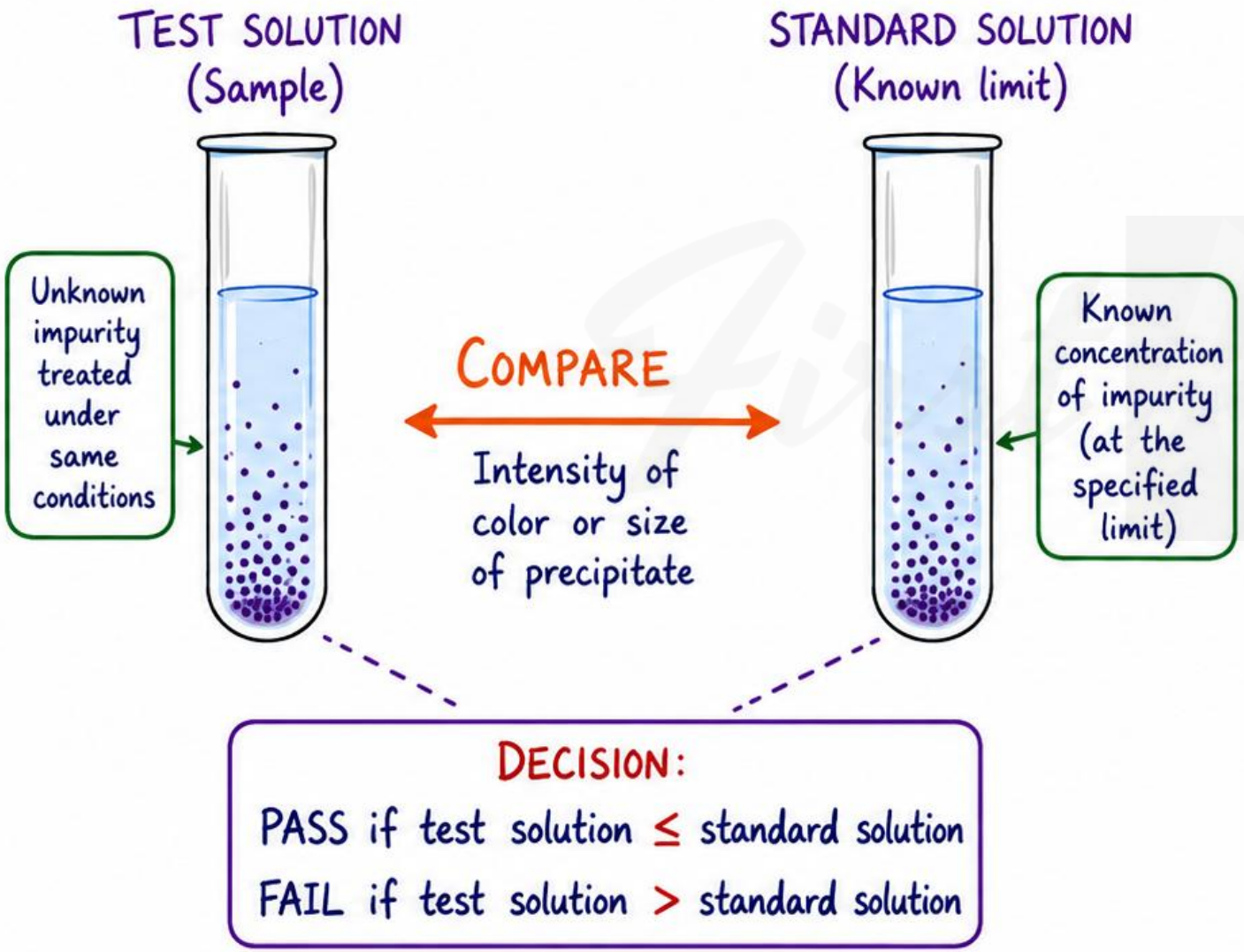
2 Types of Limit Tests:

- Qualitative: compare test with reference standard; report PASS/FAIL.
- Quantitative: measure actual concentration using analytical techniques.

3 Common Application:

- Heavy metals: ensure lead, cadmium, mercury, or arsenic are present below their acceptable limits.

Matched Test and Standard Solutions



- Limit test compares a test solution with a standard solution containing a known amount of impurity at the specified limit.
- Both are treated under identical conditions; results are matched by comparing color intensity or precipitate size.
- Pass if the test solution shows less or equal intensity (or smaller precipitate) than the standard; otherwise, fail.

Limit Test for Chloride: Principle

Principle: Chloride ions (Cl^-) react with silver ions (Ag^+) to form an insoluble white precipitate of silver chloride (AgCl). The test precipitate must be less intense (less turbid) than the reference precipitate.

1 Prepare reference solution

Known Cl^- limit (from NaCl or KCl)



Reference (limit) solution

2 Prepare test solution

Sample containing chloride ions (soluble form)



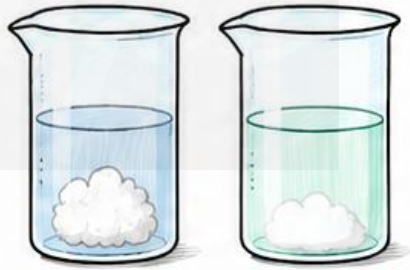
Test solution

3 Add silver nitrate solution



Reference solution | Test solution

4 Observe white precipitate (AgCl)



Reference (limit) — More intense (more turbid)

Test (sample) — Less intense (less turbid)

5 Compare and conclude

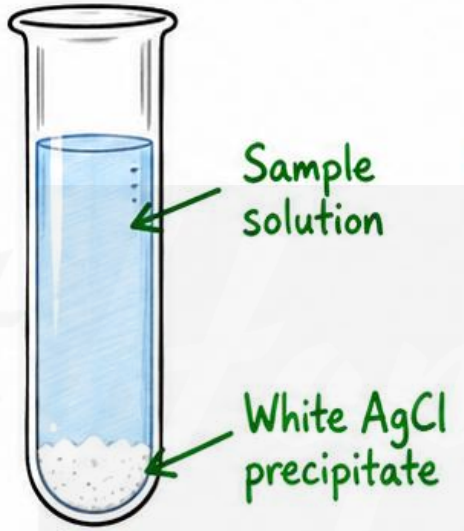
If the test precipitate is less intense or less turbid than the reference, chloride concentration is **BELOW the acceptable limit.**

$$Ag^+(aq) + Cl^-(aq) \rightarrow AgCl(s) \downarrow \text{ (white precipitate)}$$

Limit Test for Chloride: Workflow

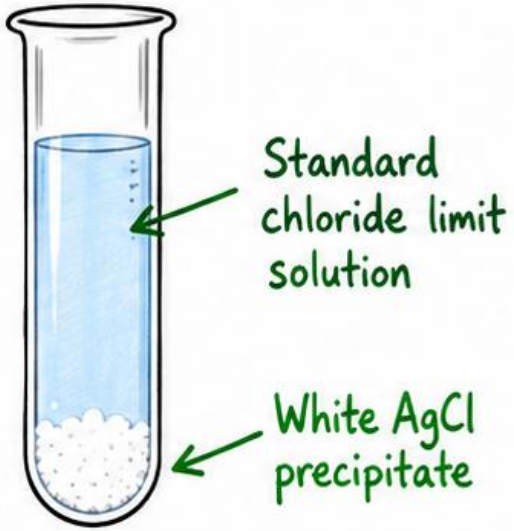
1. **Prepare Reference Solution**
   - Use standard NaCl or KCl to make a solution with known chloride limit.
2. **Prepare Test Solution**
   - Make sample solution with chloride ions in soluble form.
3. **Add Silver Nitrate**
   - Add $AgNO_3$ solution to both test and reference solutions.
4. **Formation of Precipitate**
   - White precipitate of AgCl forms if chloride ions are present.
5. **Compare & Decide**
   - Compare turbidity of test with reference to assess compliance.

Test Solution



Vs.

Reference Solution



If the precipitate in the test solution is less intense or less turbid than the reference, the chloride content is below the acceptable limit.

$$Ag^+_{(aq)} + Cl^-_{(aq)} \longrightarrow AgCl_{(s)}$$ (white precipitate)

silver ion + chloride ion → silver chloride

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