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# Lead Limit Test

Experiment 4 - Practical Notes

Name: \_\_\_\_\_ Roll no.: \_\_\_\_\_ Date: \_\_\_\_\_

## Aim

To compare the impurity response of a test preparation with the prescribed standard under matched conditions.

## Principle

A traditional lead limit test uses the coloured lead-dithizone complex under controlled extraction conditions. pH, interfering metals and the solvent phase affect the response. The test is compared with the prescribed lead standard, rather than judged simply by the presence of any colour.

## Requirements

- Prescribed monograph for the test material, impurity standard and suitable matched comparison vessels.
- Lead standard and instructor-prepared dithizone reagent system.
- Specified extraction vessels, solvent and approved laboratory controls.

## Procedure

### 1. Review the method

Identify the material, prescribed lead limit, extraction scheme and controls. The instructor provides the hazardous reagent system.

### 2. Prepare the pair

Prepare the test portion and lead-standard comparison with the specified matched conditions.

### 3. Observe extraction

Under the laboratory's controlled procedure, observe mixing, phase separation and identification of the phase containing the coloured complex.

### 4. Assess validity

Check the blank, standard and interference controls. Emulsions or incomplete phase separation must not be read as a valid test.

### 5. Compare and record

Compare the prescribed phase colour and record whether the test response exceeds the standard.

**Pharmaceutical Inorganic and Analytical Chemistry**

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**Observations and Record**

| Item                    | Required record                             | Observation |
|-------------------------|---------------------------------------------|-------------|
| Test portion / standard | Mass; impurity amount in standard           | _____       |
| Conditions              | Reagents, final amount and development time | _____       |
| Comparison              | Test versus standard response               | _____       |

**Worked Example**

The numbers below are illustrative; enter your own observations in the record.

- Illustrative comparator: 0.5 g material at 20 µg lead/g needs 10 µg lead in the standard.
- A 10 µg/mL standard supplies 10 µg in 1.0 mL. The actual monograph determines the limit and extraction conditions.

**Result**

The test response was \_\_\_\_ compared with the standard. Under valid matched conditions it \_\_\_\_ the prescribed limit; an invalid blank, standard or preparation requires repeat assessment.

**Precautions**

- Lead and the extraction reagents require the laboratory's exposure controls and segregated waste collection.
- Use instructor-prepared hazardous reagents; do not improvise masking-reagent formulas.
- Do not discard metal-containing solvent into ordinary drains.
- Use the specific substance's prescribed limit; a teaching calculation does not set the permitted impurity concentration.

**Viva Questions and Answers****1. What gives the characteristic colour?**

A lead-dithizone complex in the prescribed solvent system.

**2. Why control pH?**

Complex formation and interfering-metal behaviour depend on it.

**3. Why does phase separation matter?**

The comparison must be made in the specified phase under valid extraction conditions.

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