Pharmaceutical Inorganic Chemistry Unit I

- Impurities- It's sources, Types and Test of Purity.
- Limit Test for Chlorides, Sulphates and Iron
- Limit test for Heavy Metals

1. Impurities in pharmaceutical substances can arise from:

a) Raw materials

b) Manufacturing process

c) Storage conditions

d) All of the above

2. Which of the following is NOT a type of impurity?

a) Organic volatile impurities

b) Inorganic impurities

c) Residual solvents

d) Therapeutic impurities

3. Limit tests are designed to:

a) Quantify the exact amount of impurities

b) Determine the presence of impurities above a specified limit

c) Identify the specific type of impurity

d) Remove impurities from the substance

4. The limit test for chlorides is based on the formation of:

a) A white precipitate of silver chloride

b) A blue color with starch-iodine solution

c) A red color with potassium thiocyanate

d) A yellow precipitate with lead acetate

5. The limit test for sulfates is based on the formation of:

a) A white precipitate of barium sulfate

b) A black precipitate of lead sulfide

c) A brown color with ferric chloride

d) A yellow color with sodium nitroprusside

6. The limit test for iron is based on the formation of:

a) A blue color with potassium ferrocyanide

b) A red color with potassium thiocyanate

c) A brown color with ferric chloride

d) A yellow color with sodium nitroprusside

7. The limit test for heavy metals is based on the formation of:

a) A black precipitate with hydrogen sulfide

b) A white precipitate with silver nitrate

c) A yellow precipitate with lead acetate

d) A brown color with iodine solution

8. Which of the following is NOT a common source of heavy metal impurities?

a) Raw materials

b) Manufacturing equipment

c) Storage containers

d) Air pollution

9. The presence of impurities in a pharmaceutical substance can:

a) Affect its therapeutic efficacy

b) Increase its toxicity

c) Alter its physical and chemical properties

d) All of the above

10. Which of the following techniques can be used to detect and quantify impurities?

a) Chromatography

b) Spectroscopy

c) Titration

d) All of the above

11. The purity of a substance can be assessed by:

a) Melting point determination

b) Boiling point determination

c) Specific rotation measurement

d) All of the above

12. Which of the following is a common impurity in organic compounds?

a) Water

b) Inorganic salts

c) Residual solvents

d) All of the above

13. The presence of water in a pharmaceutical substance can:

a) Promote microbial growth

b) Accelerate degradation

c) Affect the physical properties of the substance

d) All of the above

14. Which of the following methods can be used to determine the water content of a substance?

a) Karl Fischer titration

b) Gravimetric analysis

c) Gas chromatography

d) All of the above

15. Residual solvents in pharmaceutical substances can arise from:

a) Manufacturing process

b) Purification steps

c) Storage conditions

d) All of the above

16. Which of the following techniques can be used to detect and quantify residual solvents?

a) Gas chromatography

b) Headspace gas chromatography

c) Liquid chromatography

d) All of the above

17. Organic volatile impurities (OVIs) can include:

a) Solvents

b) Reagents

c) Byproducts

d) All of the above

18. Which of the following techniques can be used to detect and quantify OVIs?

a) Gas chromatography

b) Headspace gas chromatography

c) Mass spectrometry

d) All of the above

19. Inorganic impurities can include:

a) Metals

b) Salts

c) Oxides

d) All of the above

20. Which of the following techniques can be used to detect and quantify inorganic impurities?

a) Atomic absorption spectroscopy

b) Inductively coupled plasma mass spectrometry

c) Ion chromatography

d) All of the above

21. The limit test for chlorides is typically performed on:

a) Solid dosage forms

b) Liquid dosage forms

c) Both solid and liquid dosage forms

d) None of the above

22. The limit test for sulfates is typically performed on:

a) Solid dosage forms

b) Liquid dosage forms

c) Both solid and liquid dosage forms

d) None of the above

23. The limit test for iron is typically performed on:

a) Solid dosage forms

b) Liquid dosage forms

c) Both solid and liquid dosage forms

d) None of the above

24. The limit test for heavy metals is typically performed on:

a) Solid dosage forms

b) Liquid dosage forms

c) Both solid and liquid dosage forms

d) None of the above

25. The limit test for chlorides involves the addition of:

a) Silver nitrate solution

b) Barium chloride solution

c) Potassium ferrocyanide solution

d) Hydrogen sulfide gas

26. The limit test for sulfates involves the addition of:

a) Silver nitrate solution

b) Barium chloride solution

c) Potassium ferrocyanide solution

d) Hydrogen sulfide gas

27. The limit test for iron involves the addition of:

a) Silver nitrate solution

b) Barium chloride solution

c) Potassium ferrocyanide solution

d) Hydrogen sulfide gas

28. The limit test for heavy metals involves the addition of:

a) Silver nitrate solution

b) Barium chloride solution

c) Potassium ferrocyanide solution

d) Hydrogen sulfide gas

29. The limit test for chlorides is based on the formation of a:

a) White precipitate

b) Black precipitate

c) Red precipitate

d) Yellow precipitate

30. The limit test for sulfates is based on the formation of a:

a) White precipitate

b) Black precipitate

c) Red precipitate

d) Yellow precipitate

31. The limit test for iron is based on the formation of a:

a) Blue color

b) Red color

c) Green color

d) Yellow color

32. The limit test for heavy metals is based on the formation of a:

a) Black precipitate

b) White precipitate

c) Red precipitate

d) Yellow precipitate

33. The limit test for chlorides is a:

a) Qualitative test

b) Quantitative test

c) Semi-quantitative test

d) None of the above

34. The limit test for sulfates is a:

a) Qualitative test

b) Quantitative test

c) Semi-quantitative test

d) None of the above

35. The limit test for iron is a:

a) Qualitative test

b) Quantitative test

c) Semi-quantitative test

d) None of the above

36. The limit test for heavy metals is a:

a) Qualitative test

b) Quantitative test

c) Semi-quantitative test

d) None of the above

37. The limit test for chlorides is compared to a:

a) Standard solution of known chloride concentration

b) Blank solution

c) Positive control

d) None of the above

38. The limit test for sulfates is compared to a:

a) Standard solution of known sulfate concentration

b) Blank solution

c) Positive control

d) None of the above

39. The limit test for iron is compared to a:

a) Standard solution of known iron concentration

b) Blank solution

c) Positive control

d) None of the above

40. The limit test for heavy metals is compared to a:

a) Standard solution of known heavy metal concentration

b) Blank solution

c) Positive control

d) None of the above

41. The limit test for chlorides is performed in a:

a) Nessler cylinder

b) Volumetric flask

c) Conical flask

d) Beaker

42. The limit test for sulfates is performed in a:

a) Nessler cylinder

b) Volumetric flask

c) Conical flask

d) Beaker

43. The limit test for iron is performed in a:

a) Nessler cylinder

b) Volumetric flask

c) Conical flask

d) Beaker

44. The limit test for heavy metals is performed in a:

a) Nessler cylinder

b) Volumetric flask

c) Conical flask

d) Beaker

45. Which of the following is a common limit for chlorides in pharmaceutical substances?

a) Not more than 0.01% w/w

b) Not more than 0.05% w/w

c) Not more than 0.1% w/w

d) Not more than 0.5% w/w

46. Which of the following is a common limit for sulfates in pharmaceutical substances?

a) Not more than 0.01% w/w

b) Not more than 0.05% w/w

c) Not more than 0.1% w/w

d) Not more than 0.5% w/w

47. Which of the following is a common limit for iron in pharmaceutical substances?

a) Not more than 10 ppm

b) Not more than 20 ppm

c) Not more than 50 ppm

d) Not more than 100 ppm

48. Which of the following is a common limit for heavy metals in pharmaceutical substances?

a) Not more than 10 ppm

b) Not more than 20 ppm

c) Not more than 50 ppm

d) Not more than 100 ppm

49. The limit tests are described in which pharmacopoeia?

a) United States Pharmacopeia (USP)

b) European Pharmacopoeia (Ph. Eur.)

c) British Pharmacopoeia (BP)

d) All of the above

50. Compliance with limit tests is:

a) Mandatory for all pharmaceutical substances

b) Optional for all pharmaceutical substances

c) Dependent on the specific monograph

d) Not required for any pharmaceutical substance

Answers

1. **Impurities in pharmaceutical substances can arise from raw materials, the manufacturing process, and storage conditions.**
2. **Therapeutic impurities are not a recognized type of impurity in pharmaceutical substances.**

3. **Limit tests are designed to determine the presence of impurities above a specified limit.**
4. **The limit test for chlorides is based on the formation of a white precipitate of silver chloride.**
5. **The limit test for sulfates is based on the formation of a white precipitate of barium sulfate.**
6. **The limit test for iron is based on the formation of a blue color with potassium ferrocyanide.**
7. **The limit test for heavy metals is based on the formation of a black precipitate with hydrogen sulfide.**
8. **Air pollution is not considered a common source of heavy metal impurities in pharmaceutical substances.**
9. **The presence of impurities in a pharmaceutical substance can affect its therapeutic efficacy, increase its toxicity, and alter its physical and chemical properties.**
10. **Chromatography, spectroscopy, and titration are techniques that can be used to detect and quantify impurities.**
11. **The purity of a substance can be assessed by determining its melting point, boiling point, and specific rotation.**
12. **Water, inorganic salts, and residual solvents are common impurities in organic compounds.**
13. **The presence of water in a pharmaceutical substance can promote microbial growth, accelerate degradation, and affect the physical properties of the substance.**
14. **Karl Fischer titration, gravimetric analysis, and gas chromatography are methods that can be used to determine the water content of a substance.**
15. **Residual solvents in pharmaceutical substances can arise from the manufacturing process, purification steps, and storage conditions.**
16. **Gas chromatography, headspace gas chromatography, and liquid chromatography are techniques that can be used to detect and quantify residual solvents.**
17. **Organic volatile impurities (OVIs) can include solvents, reagents, and byproducts.**
18. **Gas chromatography, headspace gas chromatography, and mass spectrometry are techniques that can be used to detect and quantify OVIs.**
19. **Inorganic impurities can include metals, salts, and oxides.**
20. **Atomic absorption spectroscopy, inductively coupled plasma mass spectrometry, and ion chromatography are techniques that can be used to detect and quantify inorganic impurities.**
21. **The limit test for chlorides is typically performed on both solid and liquid dosage forms.**
22. **The limit test for sulfates is typically performed on both solid and liquid dosage forms.**
23. **The limit test for iron is typically performed on both solid and liquid dosage forms.**

24. **The limit test for heavy metals is typically performed on both solid and liquid dosage forms.**
25. **The limit test for chlorides involves the addition of silver nitrate solution.**
26. **The limit test for sulfates involves the addition of barium chloride solution.**
27. **The limit test for iron involves the addition of potassium ferrocyanide solution.**
28. **The limit test for heavy metals involves the addition of hydrogen sulfide gas.**
29. **The limit test for chlorides is based on the formation of a white precipitate.**
30. **The limit test for sulfates is based on the formation of a white precipitate.**
31. **The limit test for iron is based on the formation of a blue color.**
32. **The limit test for heavy metals is based on the formation of a black precipitate.**
33. **The limit test for chlorides is a semi-quantitative test.**
34. **The limit test for sulfates is a semi-quantitative test.**
35. **The limit test for iron is a semi-quantitative test.**
36. **The limit test for heavy metals is a semi-quantitative test.**
37. **The limit test for chlorides is compared to a standard solution of known chloride concentration.**
38. **The limit test for sulfates is compared to a standard solution of known sulfate concentration.**
39. **The limit test for iron is compared to a standard solution of known iron concentration.**
40. **The limit test for heavy metals is compared to a standard solution of known heavy metal concentration.**
41. **The limit test for chlorides is performed in a Nessler cylinder.**
42. **The limit test for sulfates is performed in a Nessler cylinder.**
43. **The limit test for iron is performed in a conical flask.**
44. **The limit test for heavy metals is performed in a Nessler cylinder.**
45. **A common limit for chlorides in pharmaceutical substances is not more than 0.01% w/w.**
46. **A common limit for sulfates in pharmaceutical substances is not more than 0.1% w/w.**
47. **A common limit for iron in pharmaceutical substances is not more than 20 ppm.**
48. **A common limit for heavy metals in pharmaceutical substances is not more than 10 ppm.**
49. **The limit tests are described in the United States Pharmacopeia (USP), European Pharmacopoeia (Ph. Eur.), and British Pharmacopoeia (BP).**
50. **Compliance with limit tests is dependent on the specific monograph.**