**Question Bank for Chapter II: Parenteral dosage forms (FAQ): frequently asked question**

1. Distinguish between Type I and II and Type III glass
2. Why is the total solid contents of Sterile WFI is higher than WFI
3. What are the official standards of purity of purity for wfi and sterile wfi.
4. What are the sources of pyrogens. State various principles in methods of depyrogenation **(FAQ)**
5. Write a short note on LAL test/ Bacterial Endotoxin Test / Pyrogen test **FAQ)**
6. How is Clarity test & Particulate Matter test performed for Injectables solutions?
7. What is the importance of doing clarity and particulate matter test for injectable solutions?
8. How will you stabilize LVPs.
9. Give an example of stabilizer in an injectable
10. What are the methods used to stabilize a medicament.
11. What is the classification of clean room area?
12. Why tonicity of injections is adjusted. What is the requirement of tonicity with respect to different routes of injectable / parenteral administration?
13. Why is pH of parenterals adjusted
14. Comment on preservatives to be included in parenteral preparations.
15. Comment on non aqueous vehicles used in parenterals. What is the criteria for selection of non aqueous vehicles **(FAQ)**
16. What are the raw materials used in formulation of LVPs & SVPs.
17. What are physiological and physico-chemical parameters to be considered for formulation of parenterals?
18. What are the factors affecting formulation of injections. **(FAQ)**
19. How the volume of package usage and route of administration affect formulation of injections.
20. Why is strict isotonicity required for intrathecal injection?
21. Comment on packaging of LVP and SVP
22. What are the required properties of rubber closures? **(FAQ)**
23. Write briefly on processing of rubber closures **(FAQ)**
24. What is isolation or barrier technology
25. What are the advantages and limitations of freeze drying **(FAQ)**
26. What are the official tests as per IP performed on glass and plastic containers to be used for parenteral preparations?
27. What do you mean by validation of aseptic filling? What is media fill /process simulation testing?
28. How is sterility testing performed? How will you avoid false positive test. **(FAQ)**
29. What is growth promotion test in sterility testing.
30. What is FFS technology **FAQ)**
31. Elaborate on environmental control for injectable manufacturing unit **(FAQ)**
32. Discuss the layout for injectable section for manufacture of a thermo labile drug. What will be the environmental control for such facility? **(FAQ)**
33. Mention the different types of sterilizing grade filters their mechanism of actions
34. Write a short note on:
    1. Manufacturing of Water for injection and its method of depyrogenation & storage
    2. HVAC **(FAQ)**
    3. Air handling unit
    4. Laminar air flow
    5. HEPA Filters **(FAQ)**
    6. Parenteral production facility
    7. Process flow diagram of parenterals

Topic wise distribution of marks

Total there are 6 questions out of which Question 1 is compulsory

Trend shows that QNO. 1 which is compulsory includes topics Parenterals & Ophthalmics, more weightage for parenterals & ophthalmics topics

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Year | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2012 | 2013 | 2013 |
| Question & Topic |
| 1 | Parenteral 7 | Parenteral 7 | Ophthalmics 7 | Parenterals 5  Sustained release 5 | Parenterals 5  Ophthalmics 5 | Parenterals 5  Ophthalmics 5 | Parenterals 5  Ophthalmics 5 | Parenterals 10 | Parenterals 5  Ophthalmics 5 |
| 2 | Parenterals 7 | --- | Parenteral 7 | Sustained release 8 | Ophthalmics 10 | Ophthalmics 10 | Stability 10 | Ophthalmics 10 | Parenterals 10 |
| 3 | Ophthalmics 3 | Ophthalmics 7 | Ophthalmic 7 | Stability 8 | Sustained release 10 | Sustained release 10 | Ophthalmics 5  Parenterals 5 | Sustained Release 10 | Stability 5  Sustained release 5 |
| 4 | Parenterals 4 | --- | -- | Parenteral 8 | Stability 10 | Stability 10 | Sustained Release 4  Parenteral 6 | Stability 10 | Stability 5  Sustained release 5 |
| 5 | Ophthalmics 4 | Parenterals 7 | Short notes  Parenterals  7 | Ophthalmic 8 | Parenterals 5  Ophthalmics 5 | Parenterals 5  Ophthalmics 5 | Short notes (any 2)  Parenterals5  Ophthalmics 5  Sustained release5 | Parenterals 10 | Ophthalmics  10 |
| 6 | -- | Ophthalmics 4 | --  Parenterals 4 | Parenterals 5  Ophthalmic 3 | Ophthalmics 5  Parenterals 5 | Short notes (any 2)  Parenterals  Stability  Sustained release | Parenterals 5  Sustained release 5 | Short notes (any 2)  Parenterals5  Stability5  Sustained release5 | Short notes (any 2)  Parenterals  Ophthalmics  Sustained release |
| 7 | Parenterals 4  Ophthalmics 3 | Parenterals 3  --- | -- | Short notes (any 2)  Parenterals  Stability  Sustained release  Ophthalmics |  |  |  |  |  |
| Topic wise weightage | Parenteral 22  Ophthalmics  10 | Parenterals 17  Ophthalmics 11 | Parenterals 18 ophthalmics 14 | Parenterals 22  Ophthalmics | Parenterals 15  Ophthalmics 25  Sustained Release 10  Stability 10 | Parenterals 15  Ophthalmics 20  Sustained Release 15  Stability 15 | Parenterals 26  Ophthalmics 15  Sustained Release 14  Stability 10 | Parenterals 25  Ophthalmics 10  Sustained Release 15  Stability 15 | Parenterals 20  Ophthalmics 20  Sustained Release 15  Stability 10 |
| Total marks |  |  |  |  | 60 | 65 | 65 | 65 | 65 |