**8TH SEMESTER**

#### **PHARMACEUTICAL REGULATORY SCIENCES**

**LONG ESSAYS**

1. Explain in detail on DMF system in India
2. Explain the approval process and timeline for investigational new drug.
3. Define common technical document (CTD) and electronic common technical document (eCTD). Explain different modules in CTD and eCTD.
4. Explain the stages in development of new drug
5. What is CTD and eCTD. Explain the different modules of CTD in detail
6. Discuss the application and approval process for ANDA
7. Explain the stages in drug development process
8. Explain the regulatory approval process for New Drug Application.
9. Discuss briefly open part and closed part of DMF.
10. What is innovator and generic products?
11. Explain stage in development of generic formulations
12. Define CTD and discuss the process involved in its submission
13. Explain the organization and functions of regulatory bodies of EU and Australia
14. Explain the regulatory approval process for ANDA
15. Explain different stages of drug discovery
16. Explain the application and approval process of IND
17. Explain different stages involved in development of new drugs
18. Explain the organization and functions of Australia and US drug regulatory bodies
19. Explain the application and regulatory approval process for IND
20. Discuss the process of DMF system
21. Explain the different modules of CTD in detail
22. Explain the different modules of ACTD
23. Discuss the various stages involved in generic product development
24. Discuss approval process of NDA
25. Explain the organization and functions of regulatory bodies of EU and Japan
26. Discuss different stages of pre-clinical studies
27. Discuss the application and approval process of ANDA
28. Discuss the procedure for the export of the pharmaceutical products
29. Explain stages in drug development process
30. Explain different modules of ACTD.
31. Explain the organization and functions of regulatory bodies of EU and Japan

**SHORT ESSAYS:**

1. Explain code for federal regulation with respect to Part 21
2. What is CTD and eCTD? Differentiate them.
3. Explain inclusion and exclusion in clinical trials
4. Explain changes made to approved NDA
5. Explain salient features of orange book
6. Discuss the criteria for selection of human volunteers in clinical trials
7. Explain the development of clinical trial protocols.
8. Explain different stages in non-clinical studies.
9. Explain the application and approval process for IND
10. Explain the organization structure and functions of Japan drug regulatory body
11. Explain the stages of drug discovery process
12. Discuss the importance of orange book in development of generic product
13. Explain the application and approval of ANDA
14. Write briefly on clinical trial protocol
15. Explain the salient features of pharmacovigilance
16. Explain the differences between brand and generic products
17. Explain organization structure and functions of Europe drug regulatory authority
18. Write an overview on ACTD
19. Explain the non -eCTD electronic submission form (NeeS).
20. Explain the organization and functions of CDSCO
21. Explain the salient features of purple book.
22. Define clinical trial and explain Phase II
23. Explain the constitution and functions of Institutional Review Board
24. Regulatory approval process for IND
25. Explain the salient features of Pharmacovigilance
26. Write a note on ANDA and its approval process
27. Differentiate between innovator and generic products
28. Explain independent ethics committee
29. Write a note on different modules of DMF
30. Discuss salient features of orange book
31. Discuss Phase I clinical trials
32. Discuss briefly stages of drug discovery process
33. Differentiate innovator and generic products
34. Explain monitoring of clinical trials
35. Write briefly on changes made to approved ANDA
36. Write an overview on ACTD
37. Explain the eCTD.
38. Explain code of federal regulation.
39. Write a note on ANDA and its approval process.
40. Explain regulatory change over from NDA to ANDA
41. Define and explain ethical principles of informed consent process
42. Explain salient features of purple book
43. Explain independent ethics committee
44. Discuss organization structure and functions of regulatory authority for EU
45. Explain regulatory approval process of IND
46. What is clinical trial protocol? Write a note on informed consent process.
47. Write briefly on organization structure and functions of USFDA.
48. Explain the salient features of orange book.
49. Define clinical trial and explain Phase III
50. Explain the constitution and functions of Institutional Review Board
51. Write a note on 21 CFR
52. Write different modules of ACTD
53. Explain the importance of pharmacovigilance
54. Explain organization structure and functions of drug regulatory authority of Australia
55. Explain the salient features of pharmacovigilance
56. Explain the organization structure and functions of CDSCO
57. Explain the working procedure for preparation of clinical trial protocol
58. Explain the application and approval of IND
59. Explain the constitution and functions of clinical review board
60. What is CTD and explain different sections of CTD
61. Discuss the importance of orange book
62. Explain organization structure and functions of USFDA
63. Explain different changes made to an approved NDA
64. Explain CTD and eCTD
65. Explain inclusion and exclusion in clinical trials
66. Explain code for federal regulation with respect to Part 21
67. Explain changes made to approved NDA
68. Explain salient features of purple book
69. Explain the organization and functions of CDSCO
70. Explain briefly generic product development process
71. Explain the formation and functions of institutional review board
72. Briefly write a note on submission of DMF
73. Define and differentiate CTD and eCTD
74. Explain the Phase II clinical trials
75. With example differentiate between brand and generic products
76. Explain the process involved in shifting from NDA to ANDA
77. Explain the importance of 21 CFR
78. Explain the procedure for the export of generic formulations
79. Explain the inclusion and exclusion criteria in clinical trials
80. Discuss the importance of pharmaceutical regulatory affairs in industry
81. Explain the safety monitoring in clinical trials
82. Explain the organization structure and functions of Australian drug regulatory body
83. Explain code of federal regulation
84. Write briefly on the development of clinical trial protocol
85. Explain the salient features of orange book
86. Explain the formation and functions of independent ethics committee
87. What is DMF? Explain the contents of DMF
88. Explain organization structure and functions of drug regulatory authority of Japan
89. Explain the ethical principles of informed consent form for clinical trial process
90. Concept of generic drug product development

**SHORT ANSWERS:**

1. Purple book
2. Enlist different applications used for approval in EU
3. Pre-clinical studies
4. Organogram of CDSCO
5. Difference between brand and generic products
6. Difference between NDA and ANDA
7. Enlist the stages of drug development process
8. Name the regulatory authorities of India, US, EU and Australia
9. Write a note on Phase II
10. List out the items of module III in ANDA
11. Exclusion criteria in clinical trials
12. Constitution of Australian authority
13. Export of generic products
14. Process of informed consent
15. Phase II clinical trials
16. Significance of pharmacovigilance
17. Role of regulatory affairs in pharmaceutical industry
18. eCTD
19. CFR
20. Functions of US regulatory authority
21. Functions of Japan drug regulatory authority
22. Importance of DMF
23. Modules of CTD
24. Non-clinical studies
25. Functions of CDSCO
26. Non – eCTD submission form
27. Informed consent form
28. Purple book
29. Constitution of IRB
30. Module III in eCTD
31. Functions of Japan drug regulatory body
32. Salient features of DMF
33. Phase II clinical trials
34. Export of generic products
35. Institutional Review Board
36. Safety monitoring in clinical trials
37. Open parts of DMF
38. Objectives of regulatory affairs
39. Differentiate innovator and generic products
40. Functions of US FDA
41. Orange book
42. Safety monitoring in clinical trials
43. Phase I
44. Importance of DMF
45. Modules of ACTD
46. Non-clinical studies
47. Mention the general list of 21 CFR
48. Difference between CTD and eCTD
49. Give examples for brand and the respective generic products
50. Constitution of CDSCO
51. Objectives of regulatory affairs department in pharma industry
52. Enlist the types of DMF
53. Non-clinical studies
54. Pharmacovigilance
55. Differentiate innovator and generic products
56. Modules in ACTD
57. Functions of US FDA
58. What is clinical trial protocol?
59. Write a note on IND
60. Enlist the functions of CDSCO
61. What is DMF? Enlist the types
62. NDA vs ANDA
63. Enlist the different applications used for approval in USFDA
64. Role of regulatory affairs personnel in pharmaceutical industry
65. Briefly write on Phase I studies
66. Importance of purple book
67. Informed consent form
68. Mention the general list of 21 CFR
69. Non-clinical trials
70. Inclusion criteria for clinical trials
71. Phase III studies
72. Write a note on generic products
73. 21 CFR
74. Enlist the functions of TGA
75. Open parts of DMF
76. Define the term TGA and EMEA
77. List out the parts in module III
78. Non-clinical studies
79. Define regulatory affairs
80. Difference between NDA and ANDA
81. List out the items in module III in ANDA
82. Write a brief note on 21 CFR
83. Define regulatory affairs
84. Enlist the functions of Australian drug regulatory authority
85. What is clinical trial protocol?
86. Differentiate between generic and innovator products
87. Enlist parts of DMF
88. Modules of ASEAN common technical document
89. Exclusion criteria in clinical trials
90. Generic vs Innovator
91. Phase II clinical trials
92. Modules of ASEAN common technical document
93. Safety monitoring in clinical trials
94. Monitoring clinical trials
95. Define the term USFDA and EMDA
96. Pre-clinical studies
97. Salient features of purple book
98. Define the term IND and NDA