2021

Time :As in Programme

Full Marks : 75

The figures in the right-hand margin indicate marks.

*Answer **all** questions.*

1. Define the following terms. [10X2=20]
   a) NDA
   b) IND
   c) IB
   d) ISO 9000
   e) ISO 14000
   f) NABL
   g) CTD
   h) COPP
   i) CDSCO

2. Answer any two [2x10=20]
   a) Discuss in detail about pilot plant scale up techniques for tablet especially with consideration in each step.

b) Define Regulatory Affairs and discuss about Regulatory Authorities, Role of RA department with responsibility.

c) Discuss in detail about ISO 9000.

3. Answer any seven. [7x5=35]

a) Discuss about general considerations of Investigational New Drug.

b) Discuss about different steps of NDA.

c) Discuss about clinical Research protocol.

d) Discuss about different elements of TQM.

e) Discuss in detail in detail about Common Technical Document.

f) Discuss in detail about Certificate of Pharmaceutical product.

g) Discuss in detail about Central Drug Standard Control Organisation.

h) Discuss about principles behind GLP.

i) Discuss the principles behind NABL Accreditation.