9/1/24

Seat Number | | | | | | |

DAGDU-45

BP-606T

Pharmaceutical Quality Assurance

(736606)

Total Pages : 7]

Time : 3 Hours **Max. Marks : 75**

Note : (1) Do not write anything on question paper except Seat No.

(2) Draw well labelled diagram wherever necessary.

(3) *All* questions are compulsory.

(4) Figures to the right indicate full marks.

1. Multiple choice questions : 20

(i) The concept covering all the aspects that influence quality of a product is .....

(*a*) Quality control

(*b*) Good laboratory practice

(*c*) Quality Assurance

(*d*) All the above

(*ii*) The key element of TQM is .....

(*a*) Focus on the customer

(*b*) Continuous improvement

(*c*) Employee involvement

(*d*) All the above

P.T.O.

(iii) Personnel should be regularly medically examined at least ..... a year.

(a) Twice

(b) Thrice

(c) Once

(d) None of the above

(iv) The Factories Act was passed in .....

(a) 1947

(b) 1956

(c) 1948

(d) 1999

(v) Potable water should meet microbiological specification of not more than .....

(a) 100 cfu/ml

(b) 300 cfu/ml

(c) 500 cfu/ml

(d) 200 cfu/ml

(vi) Good documentation frames an essential part of ..... system.

(a) Quality assurance

(b) TQM

(c) BPR

(d) BMR

(*vii*) There should be written procedure and record keeping for action take for .....

(*a*) Validation

(*b*) Equipment celebration

(*c*) Cleaning and sanitization

(d) All the above

(*viii*) TQM and ISO both focuses on .....

(*a*) Employee

(*b*) Customer

(*c*) Supplier

(*d*) All the above

(*ix*) Which of the following IPQC is particularly employed for emulsion ?

(*a*) Zeta potential

(*b*) Sedimentation rate

(*c*) Globule size distribution

(*d*) All the above

(*x*) Which of the following tests is useful for tablet and capsules ?

(*a*) Weight variation

(*b*) Disintegration

(*c*) Dissolution

(*d*) All the above

(xi) Mark the correct order of action of ethanol as disinfecting agent on bacteria, spores and fungi .....

(a) Good-Fair-Fair

(b) Fair-Good-Fair

(c) Good-Good-Fair

(d) Good-Fair-Poor

(xii) For estimating the efficacy of disinfectant in a pharmaceutical system, suspension culture is prepared of .....

(a) Bacillus subtillis

(b) *E.coli*

(c) Staphylococcus aureus

(d) All the above

(xiii) All the sterilized glasswares should be used within ..... days of sterilisation.

(a) Four

(b) Three

(c) Five

(d) Two

(xiv) Labelling includes .....

(a) Package insert

(b) Unit Carton

(c) Shelf Carton

(d) All the above

(*xv*) Glass is not suitable for injectable preparation is .....

(*a*) Type-I

(*b*) Type-II

(*c*) Type-III

(*d*) Type-IV

(*xvi*) The term waste is defined by Environmental Protection Act in .....

(*a*) 1950

(*b*) 1964

(*c*) 1981

(*d*) 1990

(*xvii*) Which of the following should be avoided during the feed of laboratory animals ?

(*a*) Crude fibre

(*b*) Contaminated food

(*c*) Parishable items

(*d*) All the above

(*xviii*) Studies which provides systemic exposure data for the toxicity testing is called .....

(*a*) Pharmacokinetics

(*b*) Toxicokinetics

(*c*) Pharmacodynamics

(*d*) Nane the above

(*xix*) Which of the following is *not* a type of process validation ?

(*a*) Prospective Validation

(*b*) Concurrent Validation

(*c*) Extrospective Validation

(*d*) Retrospective Validation

(*xx*) Generally how many successfully completed pilot production batch are required for validation purposes ?

(*a*) One

(*b*) Two

(*c*) Three

(*d*) Four

2. Solve any *two* : 20

(*a*) Explain in brief quality assurance concept in pharmaceutical industry.

(*a*) Discuss guidelines for controls on animal house.

(*c*) Explain GMP in detail.

3. Solve any *seven* : 35

(*a*) Explain sampling plan and sampling procedure.

(*b*) Explain methods and steps of waste and scrap disposal.

(*c*) Write a note on product recall.

(*d*) Write a note on Total Quality Management.

(*e*) Explain scope of NABL accreditation.

(*f*) Write requirement and characteristics of SOP.

(*g*) Discuss IPQC tests for sterile and non-sterile dosage form.

(*h*) Define process validation and explain its types.

(*i*) Write a short note on Batch Manufacturing Record.