**DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE**

**Supplementary End Semester Examination – Summer 2022**

**Course: B. Pharmacy** **Sem: VII**

**Subject Name: Industrial Pharmacy-II** **Subject Code: BP702T**

**Max Marks: 75** **Date: 15/07/2022** **Duration: 3.45 Hr.**

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**Instructions –**

1. **All questions are compulsory**
2. **Answers to MCQs should be written in full sentences**
3. **Draw diagrams / figures wherever necessary**
4. **Figures to right indicate full marks**

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**Q. 1. Objective Type Questions = 20 x 1 = 20 (All the questions are compulsory)**

i) Which of the following is not key strategic objective of pilot plant design?

a) Formulation & Process development

b) Clinical Supply Manufacture

c) Technology Evaluation, Scale up & Transfer

d) cGMP consideration

ii)Full form of SUPAC

a) Scale up and post approval changes

b) Scale up and post approval correction

c) Scale up and periodic approval changes

d) Scale up and post assisted changes

iii) Qualification is ……

a) Regulatory requirement b) Process based approach

c) Verification of quality d) Documented verification

iv)Which of the following guideline provides principles for QRM?

a) Q8 b) Q9 c) Q10 d) Q11

v)In Drug Development NDA is

a) New Drug Application c) National Drug Application

b) New Dose application d) Novel Drug Application

vi)ANDA is applicable for

a) New drug b) Generic drug c) Synthesized drug d) Herbal Drug

vii) Scale up means?

a) Increasing Batch size b) decreasing batch size

c) Increasing Production rate d) Increasing quality of batch

viii)According to WHO, TOT stands for ……..

a) Technology of Temperature b) Technology of Technique

c) Technique of Transfer d) Transfer of technology

ix)CDER is

a) Central Drug Evaluation Research Center

b) Center for Drug Evaluation & Research

c) Central Drug Economy & Research

d) Central Drug Education & Research

x)Post Marketing Phase contains:

a) Additional Indications

b) Adverse Reaction Reporting

c) Product Defect Reporting

d) All of the above.

xi)TQM is ……. Oriented system.

a) Personnel b) Method c) System d) Procedure

xii)Quality should be built in to product by designs involved in concept.

a) TQM b) Six Sigma c) QbD d) QbT

xiii)Act for Drugs Price Control Order comes on

a) 1992 b) 1995 c) 1993 d) 1998

xiv)The guidelines & requirements for clinical trials is provided by

a) Schedule N b) Schedule K c) Schedule Y d) Schedule J

xv)Central Drugs Laboratory of CDSCO is situated at

a) Kasauli b) Kolkata c) Both A & B d) Chennai

xvi)Red colored ribbon designate the:

a) Approved drug product

b) Unapproved drug product

c) Drug Manufactured with foreign manufacturing sites

d) None of the above

xvii) Quality information for drug submission for new drug approval includes

a) Control of drug product c) Drug substance

b) Characterization d) All of the above

xviii)DCGI stands for

a) Drug Commissioner General of India

b) Deputy Commissioner General of India

c) Drugs Controller General of India

d) Deputy Commissioner General of India

xix)Who can reinstatement a Disqualified Facility according to GLP?

a) Study Director c) Drug Commissioner

b) Master Black belt Champion d) QA Head

xx)Six sigma equals ……% accuracy.

a) 99 b) 97.9999 c) 99.7999 d) 99.9997

**Q. 2. Long Answers) = 2 x 10 = 20 (Answer 2 out of 3)**

i) Explain in details pilot-Plant scale up techniques for Solid oral.

ii) Write the basic principles of ISO 9000. Explain ISO 9000 series in detail. Write a note on requirements of ISO 9000 Series.

iii) Explain Structure of Indian regulatory bodies and describe approval procedure for new drug.

**Q. 3. Short Answers = 7 x 5 = 35 (Answer 7 out of 9)**

i) What is QRM? Describe Principal and Process of QRM

ii) Explain principle involved in QBD

iii) Write a short note on SUPAC

iv) Explain toxicological approaches to drug discovery

v) Write a note on Types of IND application

vi) Describe in details Agencies for Technology Transfer (TT) in India.

vii) Explain in details six sigma concepts

viii) Write a short note on clinical research protocol.

ix) What is an NDA? Discuss the requirements of data while filing a NDA. Give examples Where a NDA can be filed.

**------END OF THE PAPER------**