Roll No.: _____ Enrolment No._____

PARUL UNIVERSITY

PARUL INSTITUTE OF PHARMACY AND RESEARCH

B.PHARM 6TH SEMESTER FIRST INTERNAL THEORY EXAMINATION: 2019-20

Subject Name: Pharmaceutical Quality Assurance
Subject Code: BP606T
Time: 2.00 PM To 3.15 PM

Date: 22/02/2020
Total Marks: 30

Instructions:

1. **Make suitable assumptions wherever necessary.**
2. **Figures to the right indicate maximum marks.**

Q.1 Multiple Choice Questions. (10 X 1=10) 10

(A) ISO is a network of national standard institutes of ____ countries.
a. 155 b. 159 c. 156 d. 158

(B) When the series of standards ISO 9000 is released
a.1987 b. 1949 c.1982 d.1986

(C) What is the full form of QTPP
a. Quality Total Profile Product b. Quality Total Product Profile
c. Quality Target Product Profile d. Quality Target Profile Product

(D) Which guideline is for QbD?
a. ICH Q8 b. ICH Q1 c. ICH Q4 d. ICH Q6

(E) Documented verification of proposed design's ability to meet the requirements it needs to fulfill is called as
a. Design qualification b. installation qualification
c. operational qualification d. performance qualification

F) The purchaser has specified 316 stainless steel as the equipment material to the equipment manufacturer. which qualification will help him to verify the material?
a. Design qualification b. installation qualification
c. operational qualification d. performance qualification

G) The closeness of agreement between the value, which is accepted either as a conventional true value or an accepted reference value and the value found is called
a. Accuracy b. precision c. robustness d. ruggedness

H) Precision is independent of accuracy
a. true b. false c. both a and b d. none of above

I) ___is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during its normal usage.
a. robustness/ ruggedness b. linearity c. precision d. system suitability testing

J) If the purchaser has specified that the equipment is going to run in a range of 50 -150 RPM and will draw a specific amount of power, how will he verify that the equipment is achieving those operational requirements?
a. Design qualification b. installation qualification
c. operational qualification d. performance qualification

Q.2 Attempt any 01 out of 02 questions. (1 X 10 =10) 10

A) Discuss in detail elements of QbD.

B) Describe in detail parameters of analytical method validation.

Q.3 Attempt any 02 out of 03 questions. (2 X 5=10) 10

A) Short note on ISO 9000.

B) Describe Responsibility and function of QA.

C) Write a short note on calibration of pH meter.