Name: **Enrolment No:**	UPES UNIVERSITY WITH A PURPOSE

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, May 2021

Course: Good Laboratory Practices and Intellectual Property Rights
Semester: II
Program: B.Sc. Clinical Research
Time : 03 hrs.
Course Code: HSCC1020 **Max. Marks: 100**
Instructions: All the sections are compulsory

SECTION A

1. Each Question will carry 1.5 Marks
2. Instruction: Answers all the 20 questions.

S. No.	Type the answer/True or False /MCQ/Fill in the blanks Questions.	**30 Marks**	**CO**
1	Mention the complete name the three terms: ICH, OECD and USFDA.	**1.5**	**CO1**
2	What is difference between copyright and trademark?	**1.5**	**CO2**
3	Write two international authentic web site/web source for patent search.	**1.5**	**CO3**
4	Following symbols are used for? (i) ®…….. (ii) **TM**……..(iii) **SM**……..	**1.5**	**CO4**
5	CQA is: (a) Critical Quality Attribute, (b) Critical Quality Angle, (c) Complex Quality Attribute, (d) Complex Quality Angle	**1.5**	**CO5**
6	Which of the following are GLP regulations or requirements? (a) 21CFR58, (b) 40CFR160, (c) 21CFR211, (d) a & c Only, (e) a & b Only	**1.5**	**CO1**
7	cGMP stands for? (a) Compendium Good Monitoring Practices, (b) Compendium Good Manufacturing Practices, (c) Current Good Manufacturing Practices, (d) Current Good Monitoring Practices	**1.5**	**CO2**
8	Which of the following type(s) of Personal Protective Equipment (PPE) is used in a good laboratory? (a) Safety glasses (b) Gloves, (c) Lab Coats and Face Shields, (d) All of the above	**1.5**	**CO3**
9	The sign (a, b and c) below indicates what type of safety hazard?	**1.5**	**CO4**

	 (a)  (b)  (c)		
10		**1.5**	**CO5**
11	"Qualitative results" refer to: (a) Results that can be observed during an experiment, (b) Results that are difficult to observe during an experiment, (c) Results that require numerical data, (d) none of these	**1.5**	**CO1**
12	Accuracy is defined as: (a) A measure of how often an experimental value can be repeated, (b) The closeness of a measured value to the real value, (c) The number of significant figures used in a measurement, (d) None of these	**1.5**	**CO2**
13	The % RSD and % Bias was calculated in the experiment to check……..	**1.5**	**CO3**
14	The Mathematical formula of the Standard Deviation is…….	**1.5**	**CO4**
15	How to calculate the Standard error?	**1.5**	**CO5**
16	In GLP practice certificate of analysis is used for……..	**1.5**	**CO1**
17	During validation, if no change of the detected amount of the analyte in a certain sample despite of the variation of the method parameter is known as……	**1.5**	**CO2**
18	Equipment Validation must be always done by ……..	**1.5**	**CO3**
19	Write the formula for calibration curve linear regression equation……..	**1.5**	**CO4**
20	Material safety data sheet (MSDS) signify the ……	**1.5**	**CO5**
SECTION B			
Q	Short Answer Type Question (5 marks each) Scan and Upload 4 questions 5 marks each	**20 Marks**	**CO**
1	Write a short notes on copyright?	**5**	**CO1**
2	What is the difference between process patent and product patent? Give one example of each.	**5**	**CO2**
3	What are different steps for filing a patent?	**5**	**CO3**
4	Explain standard approach for validation of any equipments?	**5**	**CO3**
SECTION C			
Q	**Two case studies 15 marks each subsection**	**30 Marks**	**CO**

1	**Case Study 1:** One of the largest international pharmaceutical companies i.e. Novartis International AG filed an application as per the TRIPS agreement, which is used to treat Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumor (GIST) invented from Beta crystalline form (salt form) of "Imatinib mesylate". This drug is famously used in the treatment of cancer and the same is patented in more than 35 countries except India……. (i) Write down all the possible reason why this formulation is not patented in India. (5) (ii) According to the provision of Section-3(d) of Patent Act, 1970 what is a known substance? (5) (iii) As per Novartis claim, why Imatinib mesylate is more better than Imatinib pure drug. (5)	**15**	**CO4**
2	**Case Study: 2** An Invention Disclosure Form is basically for the documentation of the invention. This is a means to document particulars of your invention and submitting it to the patent attorney who is filing your patent application. This is the primary step in disclosing an invention. It arranges the inventor's thoughts about the invention. It has to be filled in a way so that your invention is clear to the person who is unfamiliar with it. A well-written invention disclosure form enables a company to avoid non-patentable inventions. Patent preparation from the invention disclosure form will expedite the process of preparation of patent draft by the patent attorney. Patent prosecution process becomes even more productive if there is a good and productive relationship between the inventor and the patent attorney. The inventor being the expert need to cooperate with the patent attorney. (i) Write about the prior art and resources for designing/filling an patents. (5) (ii) Comments on the the existing problems of the technology that your invention proposes to solve? Have any previous attempts been made to solve these problems? (5) (iii) Write about the methodology of the invention (5)	**15**	**CO5**

	SECTION- D		
Q	Long Answer type Questions Scan and Upload (500 words for each question)	**20 Marks**	**CO**
1	(i) Write and draw the standard layout Standard Operating Procedure of Weighing Balance (5) (ii) Discuss the relevance and importance of practicing GLP in Health Research Organization. (5)	**10**	**CO1**
2	(i) Draw layout of organization chart CDSCO. (5) (ii) Write short notes on Purchase specification for raw material. (5)	**10**	**CO2**