Regd. No.:	
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## INSTITUTE OF PHARMACY

## **GITAM (Deemed to be University)**

## B. PHARMACY 6<sup>th</sup> SEMESTER – II MID SEMESTER EXAMINATION (Section A & B)

BP 606T: PHARMACEUTICAL QUALITY ASSURANCE

Date of Examination: 06.03.2020	Max Marks: 30
ne answer inside the box provided	4 ×1 = 04
pility guideline?	[ ]
(c) S1	
(d) M1	
quality certification.	[ ]
(c) ISO 9000	
(d) ISO 2000	
n analysis of historical information is known a	as [ ]
(c) Retrospective validat	ion
(d) Revalidation	
should be considered while selecting glass for	packaging in pharma?[]
(c) Leaching of alkali	
(d) All	
	$3\times 2=06$
e.	
question carries 10 marks	$1\times10=10$
ortance, scope and types of validation.	
of QbD programme.	
question carries 5 marks	$2\times 5=10$
eord.	
ol tests for glass containers.	
process.	
	te answer inside the box provided bility guideline?  (c) S1 (d) M1 quality certification.  (c) ISO 9000 (d) ISO 2000 (a) ISO 2000 (a) Retrospective validat (d) Revalidation (c) Revalidation (c) Leaching of alkali (d) All  (d) All  e.  question carries 10 marks ortance, scope and types of validation.  of QbD programme.  question carries 5 marks ord. ol tests for glass containers.

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## **GITAM (Deemed to be University)**

# B. PHARMACY 6<sup>th</sup> SEMESTER – II MID SEMESTER EXAMINATION (Section A & B)

**BP 606T: PHARMACEUTICAL QUALITY ASSURANCE** 

Time: 1 hr 10 Min.	Date of Examination: 06.03.2020	Max Marks: 30
I. Multiple Choice Questions: Writ	te the answer inside the box provided	4 ×1 = 04
1. Which of the following is ICH	stability guideline?	[ ]
(a) Q1	(c) S1	
(b) E1	(d) M1	
2. The following deals with the IS	SO quality certification.	[ ]
(a) ISO 18000	(c) ISO 9000	
(b) ISO 14000	(d) ISO 2000	
3. The documented evidence base	[ ]	
(a) Prospective validation	(c) Retrospective validatio	
(b) Concurrent validation	(d) Revalidation	
4. Which of the following propert (a) Delamination	ies should be considered while selecting glass for p  (c) Leaching of alkali	ackaging in pharma?[]
(b) Photo degradation	(d) All	
<ul><li>II. Objective Type Questions</li><li>5. Define quality audit.</li></ul>		$3\times 2=06$
6. Define calibration.		
7. What is NABL? Write its object	ctive.	
III. Answer any ONE question: Ea	ach question carries 10 marks	$1\times10=10$
8. Define validation. Discuss the i	importance, scope and types of validation.	1 ^ 10 - 10
9. Explain the elements and benef		
IV. Answer any TWO questions: E	1 0	25 10
10. Write a note on batch formula	<del>-</del>	$2\times 5=10$
11. Discuss in detail the quality co	_	
12. Describe the ICH harmonizati	on process.	