JAYAWANT SHIKSHAN PRASARAK MANDAL'S
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(Approved by PCI & AICTE, New Delhi, DTE, Govt. of Maharashtra, Mumbai, and Affiliated to Savitribai Phule Pune University, Pune) DTE Code: PH6387

Prof. T. J.SAWANT
D.E.E,B.E.(Elec.), MISTE
Founder-Secretary

Dr V.V. POTNIS
M.Pharm., Ph.D.
Principal

Date: 16/08/2019

To,
The Coordinator,
NAAC, Bengaluru.

Subject: Proof of Institution adheres to the academic calendar for the conduct of Continuous Internal Evaluation and ensures that it is robust and transparent.

Reference: 2.5.1 The Institution adheres to the academic calendar for the conduct of Continuous Internal Evaluation and ensures that it is robust and transparent.

Dear Sir/Madam,

2.5.1 The Institution adheres to the academic calendar for the conduct of Continuous Internal Evaluation and ensures that it is robust and transparent.

JSPM's Jayawantrao Sawant College of Pharmacy & Research Pune University Id No. PU / PN /B.Pharmacy/ 257/2006

PRINCIPAL
Jayawantrao Sawant
College of Pharmacy & Research
Hadapsar, Pune - 411 028

Assessed Answersheets

Jayawant Shikshan Prasarak Mandal's

JSPM's Group of Institute

Name of Institute _____

Varified & all the entries found correct

15/2/19

Jr.Superviso's Name, Signature & Date

A-

Roll No. (In Figures) 08 Centre JSCOPR

Roll No. (In Words) Eight

Day & Date : Friday 15/02/19 Examination : 1st Insemester Assessment

Subject : Quality Assurance Section : -

Course / Paper No. : - Medium of Answer : English

Main Ans. Book + No. Of Suppliments : _____ Total

Question No.	1	2	3	4	5	6	7	8	9	10	Total	Sign.of Examiner
Marks Obtained	-										5/10	

Kajal seen

Use of coloured pencil or ink is strictly prohibited except in case of diagrams and sketches
(Write on both sides and start writing on this page.)

1. Write funct° of QA department
2. Discuss types of p'ceutical plant audit
3. Write difference bet° QA & QC
4. Explain req. of qualification & experience of person in cGMP.
5. Define GMP, GDP, GLP
6. State importance of staff training
7. What is BPCR & MPCR, state it's importance.

Answers.

(7) BPCR - (Batch Production & Control Record

Batch Production & control record of each intermediate / API / final product include complete information relating to the control and production in the quality units. The Batch control record should be checked Before the issuance to assure that it is correct version of the manufacturing process within the firm of instruction.

Importance - It ensure that the manufacturing process is suitable to particular batch of the product.

MPCR - (Master production & Master instruction control Record)

To ensure that the uniformity from batch to batch, the master control instruction intended for the intermediate, API or final product should be prepared, dated & signed by the one person and independently checked, dated & signed by the second person in the quality unit.

Importance - It ensures the uniformity from batch to batch. Master formulae is used as reference

(3) QA	QC
(1) QA is a company based process	(1) QC is a laboratory based process.
(2) QA is a review & approval of the manufacturing process & procedures and independently involve auditing & performing records.	(2) QC is testing of the processing material & finished product to evaluate the manufacturing process.
(5) QA is the total organized arrangement made ē obj. or ensuring pdt. will be Quality req.	(3) QC is the part of GMP is concerned ē sampling specification, testing with in the organization.
(4) It is planned or systemic action	(4) It is operational lab. tech & activitie.
(5) It is approved test, method, standards. ensure high standard.	(5) It is one compartment of multicompartment.
(6) It is establish method or test of checked product	(6) It is authentic testing of product or batch of product.

(5) GMP -

Good manufacturing practices are done under the schedule M according to ICH guideline. GMP guidelines are to the part of the QA ē ensure that the pdt are consistently manufactured & controlled to quality Stds.

GLP - Good laboratory practices - It concern c the organizational process & conditions ē which the laboratory studies are planned, performed, recorded & reported

GDP - Good Documentation Practices

It is for the storage & retention of the

Supervisor's Name _____
Signature & Date _____
Roll No. _____

Pg./Suppl.No:
Date:

reference material for further use.

① functions of QA department.

(1) Review & approval of the manufacturing process

(2) Record, auditing & performance determination

[Total No. of Questions: 10] [Total No. of Pages: 1]

JSCOPR-[1018] CM1-8119
Final Year B. Pharmacy
4.7.2 T – Quality assurance techniques.
(2015 Credit Pattern)

7/10

Date:30/03/2019 Time: 0.5 Hr. Max. Marks: 10

Syllabus:

1 Quality Assurance 2 Validation 3. ICH guidelines for stability testing
4. Documentation and records

Instructions to the Candidates:

All questions are compulsory. Each question carries 01 mark.

Q.	Mention the correct option in the given answer box:	Ans.
1.	Which of the following is an example of QA? A)Verification B) Software testing C)Validation D) Documentation	D
2.	Equipment LOG is A) Log of various operations carried out on equipment. B) Information of Equipment. C) SOP on Equipment D) None of above.	A
3.	In quality control activity Which are activities involved A) Sampling B) Testing C) I.P.Q.C D) All of above	D
4.	What does QA and QC stand for? A) Quality Assurance and Queuing Control B) Quality Adjustment and Quality completion C) Quality Assurance and Quality control D) Quality Adjustment and Queuing control	C
5.	PMD is A) Pharmaceutical Manufacturing Documentation. B) Packaging Material Documentation C) Programme Material Documentation. D)None of above.	B
6.	The Therapeutic Goods Administration is the regulatory body for therapeutic goods in A) India B)Australia C) China D)Japan	B
7.	Validation done during product development stage is A) Prospective Validation B) Process Validation C) Cleaning Validation D) None of above	B
8.	For analytical method,' The degree of agreement among individual test results when the method is applied repeatedly to multiple sampling of a homogenous sample." Is defined as A) Accuracy B) Precision C) Specificity D) Linearity	C
9.	URS is A) User requirement Specifications. B) User requirement Storage. C) User requirement Samples. D) None of above.	A
10.	A Complete and factual information regarding a site of pharmaceutical manufacturing plant is A) Site Master File B) Site Maintenance File C) Site Measurement File D) None of above.	A

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