

B. Pharmacy 4th yr. 1st Semester Examination 2019

Sub: Industrial Pharmacy (Newer Drugs & Biotechnological Applications)

Time: 3 Hrs.

Full Marks: 100

Answer any five questions taking at least one from each group

Group-A

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| 1. | a) Briefly discuss- In process quality control of Pharmaceuticals and its significance. | 16 |
| | b) What is Milli Q Water? | 4 |
| 2. | a) Write in short: the cold chain maintenance of pharmaceuticals. | 15 |
| | b) What is formal treated toxoid vaccine? | 5 |
| 3. | a) Describe the Sterility testing procedure of Eye drop as per I.P. guidelines. | 16 |
| | b) What is DOP/PAO test? | 4 |

B. PHARMACY FOURTH YEAR FIRST SEMESTER EXAMINATION – 2019

**Subject : INDUSTRIAL PHARMACY,
NEWER DRUGS AND
BIOTECHNOLOGICAL APPLICATIONS**

Time : Three hours

Full Marks : 100

Group : B

Instructions: Answer any five questions, taking at least one from each group.

- 4. Write the distribution and use of Fig plants found in nature. How will you isolate the Lupeol acetate from *Ficus glomerata* Roxb. leaves? 20**
- 5. Write notes on :**
- a) Micrometry
 - b) Extraction of starch from potato
 - c) Extraction of caffeine from tea
 - d) Swelling factor 20

B. PHARM 4th YEAR 1ST SEMESTER EXAMINATION, 2019

SUBJECT: ELECTIVE I (Industrial Pharmacy, Newer Drugs and Biotechnological Application)

GROUP - C

- 6 (a) Give a schematic presentation of the processes involved for approval of ANDA. 10
(b) What standards does ANDA product need to meet? Define NDA and BLA. 5+5
7. (a) What do you understand by exclusivity rights? Why is it given according to Hatch – Waxman Act. What is the exclusivity for orphan drugs? 3+4+3
(b) Elaborate Hatch – Waxman Trade – Off? What are the main factors for delay of generic entry into the market? Explain. 4+6