

SIYANA-I (C.B.C.S.) WINTER - 2015
SUBJECT: ADVANCE CORE SUBJECT-I: f) ADVANCED QUALITY ASSURANCE
TECHNIQUES-I

Day: **Friday**
Date: **08-01-2016**

Time: **10:00AM-TO 1:00 P.M.**
Max. Marks: 60

N.B.:

- 1) Attempt any **THREE** questions each from Section-I and Section-II.
- 2) Figures to the **RIGHT** indicate full marks.

SECTION-I

- Q.1** What are the major steps involved in outsourcing of manufacturing operations. (10)
- Q.2** Discuss principles involved in purchasing of materials in pharmaceutical manufacturing plant. (10)
- Q.3** Discuss design, site location and construction, requirements of equipment in detail. (10)
- Q.4** Write short notes on any **TWO** of the following: (10)
- a) Personnel selection and training
 - b) Reference and working standards
 - c) Waste material management

SECTION-II

- Q.5** Discuss in detail manufacturing aspects of sterile pharmaceutical products. (10)
- Q.6** Define cross contamination and elaborate on avoiding it in pharmaceutical production. (10)
- Q.7** Briefly discuss documents and formats in pharmaceutical manufacturing operations. (10)
- Q.8** Write short notes on any **TWO** of the following: (10)
- a) Recalled products
 - b) Process deviations
 - c) Manufacturing of biological products.