

SINGHAGAD/ AMAZON/ PARANA/ KARNAFUL/ SURAMA/ SIYANA/ PALGAD-II  
(CBCS 2012 COURSE); SUMMER -2016  
SUBJECT: Elective- II: B) IPR & REGULATORY AFFAIRS

Day: *Thursday*  
Date: *07-07-2016*

Time: *10.00 AM To 1.00*  
Max Marks: 60 *P.M*

---

**N.B:**

- 1) Attempt any **THREE** questions from each section.
  - 2) All questions carry **EQUAL** marks.
  - 3) Write each section on different answer sheets.
- 

**SECTION-I**

- Q.1** Discuss exclusion under Section 3 & 4 of Indian patent Act, 1970. (10)
- Q.2** Discuss Drug Price Control Order 1995. Discuss latest amendments to this act. (10)
- Q.3** Discuss 3 criteria for patentability. Discuss disclosure requirements for a patent under US Patent Act. (10)
- Q.4** Write short notes on any ( **TWO** ) of the following: (10)
- a) Narcotic drugs & Psychotropic Substances Act, 1985
  - b) Patent Term Extension
  - c) Factory Act

**SECTION-II**

- Q.5** Discuss various types of pharmaceutical audits with special emphasis on internal audit. (10)
- Q.6** Discuss various methods adopted for disposal of various types of pharmaceutical waste. (10)
- Q.7** Discuss control of contract manufacturing in detail. (10)
- Q.8** Write short notes on any ( **TWO** ) of the following: (10)
- a) Biomedical Waste Rules 1998
  - b) Categorization of pharmaceutical industry as per EPA
  - c) Regulatory Audits

\* \* \* \* \*

