CODE No.07601

[Time: 3 Hours] **[Marks: 80**

Please check whether you have got the right question paper.

N.B: 1. All Questions are Compulsory.
2. Answer all sub questions together.

Q.1 (a) Explain the term **(Any Five):** **05**

(i) Job description
(ii) Expiry Date
(iii) TQM tool
(iv) Quality audit
(v) GMP
(vi) Recalled product

Q.1 (b) Match the following: **05**

(i)	Triple role concept	(a) Four Phases
(ii)	Audit Cycle	(b) Post operations activity
(iii)	BPCR	(c) Quality Control tool
(iv)	Analytical outsourcing	(d) Input-process-Output
(v)	Pareto Chart	(e) Batch production & control record

Q.1 (c) Answer the following **(Any Five):** **10**

(i) Explain significance of drug product inspection.
(ii) Explain concept of "line clearance".
(iii) Comment on Internal Security.
(iv) Explain Good laboratory practices.
(v) Explain in brief Quality assurance.
(vi) Give contents of Standard Operating Procedure.

Q.2 (a) Give specifications & guidelines for personal hygiene & gowning **04**
(b) Explain concept of yield calculation & Expiry dating of coated tablet **04**
(c) Explain in brief types of audit. **04**

Q.3 (a) Explain any 4 quality control tools **04**
(b) Explain procedure to be followed to recovery of rejected material as per guidelines. **04**
(c) Write a note on Good Warehouse practices **04**

Q.4 (a) Explain process followed to control contamination with respect to environmental control **04**
(b) Give the salient features of IPQC in production & packaging **04**
(c) What are the content of master production & control records **04**

Q.5 (a) Explain the need & effect of Quality Control of API's in pharmaceutical industry. **04**
(b) What all measures to be taken for handling & storage of reference standards **04**
(c) Write a note on production management. **04**

Q.6 (a) Elaborate on procedure for handling complaints with reference to post operational activity **04**
(b) Explain regulatory guidelines to be followed for sanitation in pharmaceutical unit. **04**
(c) Explain impact of written procedures on production & process control as per GMP. **04**
