**M. Pharm II Semester**

**Clinical Research and PV**

**Assignment 10**

Q1. Describe guidelines for preparation of protocol documentation.

Q2. Discuss methods for Severity and seriousness assessment of adverse drug reaction.

Q3. Explain the Case study report and discuss its contents.

Q4. What is active and passive surveillance? Discuss comparative observational studies in detail.

Q5. Write about the WHO International drug monitoring program.