Plan of Work

1) Review of Literature
2) Collection of Materials
3) Preparation of Suppositories
4) Mould Calibration
5) Physical Appearance
6) Weight Uniformity
7) Drug Content Uniformity
8) Melting Range(time) test
9) Softening Time
10) In vitro drug release
11) Stability studies
12) Drug excipient interaction
13) Thermal analysis(Differential scanning colorimetry)

Methodology

Review of literature

Literature review is very essential part of the research work and is requires until the completion of the work. The literature survey have been performed utilizing various standard books, official books such as IP, BP USP etc., and also the journals and the e-journals have been referred for the present work.

Collection of Materials

Atenolol was a generous gift from Glenmark Pharmaceuticals, Nasik, Maharashtra, India. propylene glycol, polyethylene glycol 400 (PEG 400) was procured from Sd Fine Chem Ltd, Mumbai. Gelatin,
propyl paraben were purchased from Qualigens Fine Chemicals, Loba Chemie Pvt Ltd and Merck Specialities Pvt Ltd, Mumbai respectively. All other chemicals were of analytical reagent grade.

**Preparation of Suppositories**

The suppositories will be prepared by fusion method by using hydrophobic and hydrophilic polymers such as hydrogenated vegetable oil, Glycero-gelatin and PEG’s.

**Mould Calibration**

To avoid the variation in the mould capacity the moulds were calibrated before preparing the suppositories and were standardized. The melted base was poured into the mould and freeze dried, after freezing the suppositories were removed from the mould and weighed individually and the mean weight was taken as true capacity of the mould.

**Physical Appearance**

The physical appearance of the suppositories will evaluated as per USP-30/NF-25.

**Weight Uniformity**

The weight uniformity of the suppositories will be carried out as per USP-30/NF-25.

**Drug Content Uniformity**

Drug content uniformity of prepared suppositories is determined as per USP-30/NF-25.

**Melting Range(time ) test:**

The time taken by the suppository to melt completely when immersed in constant water bath temperature 37°±1°C is called as melting range of the suppositories and is measured using tablet disintegration test apparatus.

**Softening (Time) test**

The softening test is intended to determine the time which elapses until a suppository maintained in water softens to the extent that it no longer offers resistance when a defined weight is applied.
The softening of the suppositories is carried by using the apparatus as described in British Pharmacopoeia 1198.

**In Vitro drug release study:**

In vitro drug release studies will be carried out up to 4 hours using USP tablet dissolution test apparatus using basket stirrer. The dissolution medium (900 ml) is maintained at 37°C ± 1°C. The samples withdrawn at specified intervals will be assayed for percent drug release spectrophotometrically.

**Stability studies:**

Stability studies if the promising suppository formulations will be carried out at 4°C (refrigerator) and at room temperature (25 ± 1°C) over a period of six months.

**Drug-Excipient interaction:**

FT-IR studies will be conducted to study the drug excipient interaction.

**Differential Scanning Colorimetry (DSC):**

DSC studies will be carried out to study the thermal behavior of the drug and possible interaction.