7.0 CONCLUSION

The selected sustain release bilayer formulation gave better plasma concentration over longer period of time that will overcome the drawbacks associated with conventional frequent dosage therapy. The developed formulation also showed good relative bioavailability.

- In current study formulation of sustain release bilayer tablets successfully analysed, prepared by three different method. All methods have their distinctive characteristics.

- Simultaneous estimation method developed and validated that provided precise determination of both drug in different dissolution media.

- All three methods require attention for their respective techniques. In dry granulation compaction for granulation, binder’s type and strength and drug’s properties were important consideration. In wet granulation, binder, granulating fluid, rate of binder addition and filler were important consideration. In melt granulation type of melt binder, binder’s amount and rate of cooling were important considerations.

- From three formulations, wet granulation and melt granulation gave both good drug release profile and optimized formulation. In all methods melt granulation technique gave least % friability and good hardness.

- The *in vivo* pharmacokinetic study for optimised wet granulation and melt granulation technique compare to marketed formulation was carried out. The results showed that melt granulation technique gave better relative bioavailability.

- SR formulation with melt granulation technique in comparisons to wet granulation technique,
  - Do not use organic solvent that is costly and not safe to human and environments.
  - It does not required time for drying of granules.
  - Fewer processing steps.
Thus help productivity.

- It eliminates and/or reduces use of release retarding polymer.

- Thus help in reducing cost of formulation

- Thus an optimised SR Bilayer tablet by melt granulation technique is a promising formulation technique.

- The selected sustain release bilayer formulation will provide

  - Better plasma concentration over longer period of time that will overcome the drawbacks associated with conventional frequent dosage therapy.

  - Drug release for 12 h

  - Reduced pill burden

  - Better bioavailability

  - Improved Stability

  - Reduction in overall cost

  - Patient convenience, adherence, and compliance

- **Future Perspective:**

  The developed formulation showed good relative bioavailability although absolute and relative bioavailability study on human volunteers to establish its potential on human may provide further comparison.