CHAPTER 8

SUMMARY AND CONCLUSION

Studies were performed in the formulation and evaluation of solid dispersions of nisoldipine and amlodipine besylate with a view of developing fast dissolving tablets of nisoldipine and fast dissolving tablets of amlodipine besylate. The solid dispersions were prepared by employing solid dispersion technology using poloxamer 407 and poloxamer 188 as hydrophilic carriers. Various drug carrier ratios such as 1:1, 1:2, 1:3, 1:4 and 1:5 were utilized for preparing SDs.

From the infrared spectral analysis, it was understood that there was no significant interaction between drugs and the carriers incorporated in solid dispersions. The drug content of solid dispersions was uniform in all batches.

X-ray diffraction studies revealed that the crystalline nature of pure drugs nisoldipine and amlodipine besylate was reduced in the solid dispersions. This might be the reason for improved dissolution and also indicated the amorphous character of the prepared solid dispersions. The SEM analysis revealed that the drug is uniformly dispersed in solid dispersions.

Results of dissolution studies showed the rapid and fast dissolution of nisoldipine and amlodipine besylate from all their solid dispersions when compared with the pure drug. Poloxamer 407 which was used as a carrier in the ratio of 1:5 in solid dispersions gave the highest drug release.

The solid dispersions of nisoldipine and solid dispersions of amlodipine besylate with poloxamer 407 in the ratio of 1:5 were formulated into fast dissolving tablets using various proportions of sodium starch glycolate, croscarmellose sodium and crospovidone as superdisintegrants. The in vitro drug release profile of fast dissolving tablets was found to be increased with increase in superdisintegrant level.

The tablet formulations which showed highest drug release (NF6 and AF3) were stored in climate chambers at 40°C±2°C /75%RH ±5% relative humidity (RH) for 6 months. There were no significant changes observed in physical parameters and drug release pattern of formulated batches NF6 and AF3 under the test period. It was determined that the formulated tablets were found to be stable under storage
conditions. The comparison of dissolution profiles of amlodipine besylate FDT (AF3) with marketed tablet clearly showed the rapid and fast release of drug from formulated tablet.

The formulation of fast dissolving tablets by using the solid dispersion of nisoldipine and amlodipine besylate is a promising method. This can be useful because it has the advantage that the rate of dissolution of the drug can be rapidly increased. Therefore, it can be concluded that the combination of solid dispersion technology as well as using superdisintergrants in tablet formulation is an encouraging and effective technique to prepare efficient FDT of poorly water soluble drugs nisoldipine and amlodipine besylate.