4.0 Summary and conclusion.

In this current study, Galantamine was chosen as model drug because the existing market product of galantamine is not available in the form of mouth dissolving tablets that can deliver drug for extended period. Galantamine is indicated for mild to moderate dementia of Alzheimer.

Currently available formulations for galantamine are in the form of pellets, capsules for extended release and conventional tablets for immediate release since it becomes uneasy to swallow such dosage form for elderly patients. By looking at target population for Galantamine, orodispersible tablet with extended release profile could be favorable option that could administer the dosage form easily.

Preformulation studies were carried out during the early stages of this work. Drug excipients compatibility studies revealed that, polymers and excipients used were compatible with drug. Extended release pellets were formulated using wurster process. Drug coating of drug was done on Celphere CP 203 with the help of Povidone K30 as a binder. Extended release coatings on drug loaded pellets were done using eudragit NE 30D as a rate limiting polymer. About 30% extended release coating with eudragit NE 30D showed comparable drug release pattern that of with marketed preparation’s pellets of Galantamine ER capsules which is having similarity factor more than 70.00. Also optimization was done for percentage of extended release coating using one factor at a time (OFAT) approach. Further curing study on extended release pellets showed a bit slower dissolution rate but that is not having that much of big difference that would merely differ from marketed preparation drug release. Further these pellets were compressed tablets that were dispersed within 30 seconds, releasing extended release pellets. These formulations showed ideal drug release comparable to precompressed pellets. It showed no rupture of extended release pellets that can hamper the drug release pattern. At accelerated stability conditions developed formulations were found to be stable for six month. Also this formulation optimized using full factorial design having 2 factors (percentage of ER coating and amount of disintegrant).
Thus it had been concluded that the orodispersible Galantamine hydrobromide extended release tablet 24 mg, was formulated, optimized and comparable with existing dosage form of marketed product of galantamine. Henceforth objectives were accomplished in these thesis.