# 9. SUMMARY AND CONCLUSION

## 9. 1. Summary

- Here five newer hypolipidemic drugs (EZE, SIMVA, LOVA, PRAVA and ROSU) and its combination were selected for the study.
- Spectroscopic methods (zero order, three wavelengths, 1st and 2nd order derivative and difference) were developed for the analysis of EZE, SIMVA, LOVA, PRAVA and ROSU individually in bulk as well as in their pharmaceutical formulations.
- Quantitative FT IR methods were developed for the individual estimation of EZE, SIMVA, LOVA, PRAVA and ROSU in bulk as well as in their pharmaceutical formulations.
- Stability indicating RP-HPLC methods were developed for the EZE, SIMVA, LOVA, PRAVA and ROSU.
- Bioanalytical RP-HPLC methods were developed for the EZE, SIMVA, LOVA, PRAVA and ROSU in human plasma.
- HPTLC methods were developed for estimation of EZE, SIMVA, LOVA, PRAVA and ROSU in bulk as well as in their pharmaceutical formulations.
- HPTLC methods were developed for estimation of EZE, SIMVA, LOVA, PRAVA and ROSU in presence of its degraded products.
- Simultaneous spectroscopy and simultaneous quantitative FTIR methods were developed for EZE and SIMVA, EZE and PRAVA, EZE and ROSU, EZE and LOVA.
- HPLC and HPTLC method were developed for simultaneous estimation of EZE and SIMVA, EZE and PRAVA, EZE and ROSU, EZE and LOVA in pharmaceutical formulation.
- HPTLC method was developed for the SIMVA and NICO
- Stability indicating HPLC method was developed for EZE and SIMVA, EZE and PRAVA, EZE and ROSU, EZE and LOVA.
- Chemometric approach was used to estimate of EZE and SIMVA, EZE and PRAVA, EZE and ROSU, EZE and LOVA in pharmaceutical formulation.
- The newly developed methods were validated for specificity, linearity, accuracy, repeatability, intra day; inter day precision, limit of detection and limit of quantification.

- ❖ Statistical comparison of assay result of tablet dosage form by student's paired 't' test and ANOVA was performing for the methods.

## 9. 2. Conclusion

- ❖ All the developed methods enable the quantitation of drug alone or in a binary mixture with good accuracy & precision, either in laboratory prepared samples or in commercial pharmaceutical dosage forms.
- ❖ Quantitative IR spectroscopic method proves to be specific and selective analytical method.
- ❖ Derivative zero crossing method resolves the simultaneous estimation of drugs form their mixture with overlapped spectra with a considerable accuracy and sensitivity. It shows some limitations in the sense that this method needs the correct optimization of the method parameters.
- ❖ Chemometric methods do not imply any pretreatment such as separation procedure in HPLC, derivation of spectrum and divisor of the spectrum. The techniques are very easy to apply, though require data processing with software and its application to the regression analysis.
- ❖ HPLC and HPTLC method was used to separate combination drug and also, it could be estimate drug in presence of its degradation products. Both methods have applicability as stability indicating method.

**By the study of stability of EZE, SIMVA, LOVA, ROSU and PRAVA, it can be concluded that ------**

- ❖ EZE is degraded in neutral, acidic and basic conditions. It is stable against oxidation, light and heat.
- ❖ EZE in presence of water gets converted in to main degradation product at Rt 8.883 (Fig. 7.1.1.6.6.(C)) formed almost as a single compound in alkaline and water was isolated and characterized as (*2 *,3 *,6 **)-,6- bis(4-fluorophenyl)-2-(4-hydroxyphenyl)-3,4,5,6-tetrahydro-*2*-pyran-3-carboxamid through crystallographic studies.
- ❖ In different degradation condition EZE under go nine minor degradation products.
- ❖ SIMVA and LOVA are prodrug and in presence of acidic, neutral and basic conditions, these are converted in active lactone of acid. Prodrug and lacton of acid both can be analyzed by both developed HPLC and HPTLC methods.

- SIMVA and LOVA are stable against heat, light and oxidation.
- PRAVA is stable against heat, light and moisture, while it have hydrolysis in acid and basic medium and also oxidized.
- PRAVA is degraded into four degraded products under different degradation conditions.
- ROSU is stable against neutral and alkaline condition, while it hydrolysis by acidic medium. ROSU was affected by oxidation and heat. In presence of light it under go degradation and produce two minor products.
- ROSU is degraded into seven minor degraded products under different degradation conditions.

**The developed method suggest that-**

- All stability indicating Chromatographic methods for estimation of SIMVA and LOVA suggest that it could be used for metabolic study, bioequivalence study, estimation of SIMVA and LOVA in human volunteer can also possible.
- Stability indicating method of PRAVA, ROSU and EZE suggest that it could be used for the estimation of degraded sample and also help in synthetic path way.
- Spectrophotometric method developed for the simultaneous and individual estimation of drug suggest that it is advance method of Spectrophotometric and it haven't more complicated solvent preparation and less time consuming and economic for small scale industry.
- Quantitative FTIR method was help in estimating drug without any pretreatment and without solvent consumptions.