CHAPTER 7
SUMMARY, CONCLUSION AND
FUTURE WORK
## CHAPTER 7
### SUMMARY, CONCLUSION AND FUTURE WORK

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CHAPTER 7
SUMMARY, CONCLUSION AND FUTURE WORK

7.1. SUMMARY AND CONCLUSION FOR RABEPRAZOLE AND DOMPERIDONE:

A novel, rapid and stability indicating analytical method is developed and validated for simultaneous quantification of Rabeprazole and Domperidone in bulk and its Pharmaceutical formulations by RP-UPLC technique. So far no such method was reported in the existing literature. The developed method exhibits faster elution and better separation compared with conventional HPLC. Moreover, the less solvent consumption and short run time that allows the analysis of huge number of samples with good precision and accuracy in a short period of time, so it is affordable, convenient and economical for routine pharmaceutical analysis. The application of this method in routine analysis can be justified since easy sample preparation steps are involved using mobile phase solvent system and low costs of reagents used. There is no separate solvent system required for standard and sample solution preparations. This method will be useful for a rapid analytical procedure of the simultaneous quantitation of Rabeprazole and Domperidone in bulk and its combined dosage form.

The method was applied for determination of potency of commercial product of Rabeprazole and Domperidone and potency was found within limit. The results of assay analysis of two drugs from a combined dosage form using this developed method were found to be close to 100%. Recovery studies were satisfactory which shows that there is no interference of excipients.

The analytical procedure developed has shown satisfactory results for all the validation parameters according to ICH guidelines. The developed method was specific as no interference of excipients was found. The developed method proved to be sensitive, reproducible, precise, linear, accurate, robust, rugged, low amount of detection and low amount of quantification.

The information presented in the study could be very useful in quality control, content uniformity test, invitro dissolution of combination of Rabeprazole and Domperidone drug products.
The developed method can be efficiently applied for the separation of the drugs from its excipients and its degradation components in its pharmaceutical formulation. It can be used to check rapid and accurate drug quality during stability testing. The method can be used in the analysis of stability samples obtained during accelerated stability studies, as no interference was found with the degradants formed under various stress conditions.

7.2. SUMMARY AND CONCLUSION FOR METOLAZONE AND SPIRONOLACTONE:

A novel, rapid and stability indicating analytical method is developed and validated for simultaneous quantification of Metolazone and Spironolactone in bulk and its Pharmaceutical formulations by RP-UPLC technique. So far no such method was reported in the existing literature. The developed method exhibits faster elution and better separation compared with conventional HPLC. Moreover, the less solvent consumption and short run time that allows the analysis of huge number of samples with good precision and accuracy in a short period of time, so it is affordable, convenient and economical for routine pharmaceutical analysis. The application of this method in routine analysis can be justified since easy sample preparations steps are involved using mobile phase solvent system and low costs of reagents used. There is no separate solvent system required for standard and sample solution preparations. This method can be useful for a rapid analytical procedure of the simultaneous quantitation of Metolazone and Spironolactone in bulk and its combined dosage form.

The method was applied for determination of potency of commercial product of Metolazone and Spironolactone and potency was found within limit. The results of assay analysis of two drugs from a combined dosage form using this developed method were found to close to 100%. Recovery studies were satisfactory which shows that there is no interference of excipients.

The analytical procedure developed has shown a satisfactory results for all the validation parameters according to ICH guidelines. The developed method was specific as no interference of excipients was found. The developed method proved to be sensitive, reproducible, precise, linear, accurate, robust, rugged, low amount of detection and low amount of quantification.
The information presented in the study could be very useful in quality control, content uniformity test, in vitro dissolution of combination of Metolazone and Spironolactone drug products.

The developed method can be efficiently applied for the separation of the drugs from its excipients and its degradation components in its pharmaceutical formulation. It can be used to check rapid and accurate drug quality during stability testing. The method can be used in the analysis of stability samples obtained during accelerated stability studies, as no interference was found with the degradants formed under various stress conditions.

7.3 SUMMARY AND CONCLUSION FOR DULOXETINE AND MECOBALAMIN:

A novel, rapid and stability indicating analytical method is developed and validated for simultaneous quantification of Duloxetine and Mecobalamin in bulk and its Pharmaceutical formulations by RP-UPLC technique. So far no such method was reported in the existing literature. The developed method exhibits faster elution and better separation compared with conventional HPLC. Moreover, the less solvent consumption and short run time that allows the analysis of huge number of samples with good precision and accuracy in a short period of time, so it is affordable, convenient and economical for routine pharmaceutical analysis. The application of this method in routine analysis can be justified since easy sample preparations steps are involved using mobile phase solvent system and low costs of reagents used. There is no separate solvent system required for standard and sample solution preparations. This method can be useful for a rapid analytical procedure of the simultaneous quantitation of Duloxetine and Mecobalamin in bulk and its combined dosage form.

The method was applied for determination of potency of commercial product of Duloxetine and Mecobalamin and potency was found within limit. The results of assay analysis of two drugs from a combined dosage form using this developed method were found to close to 100 %. Recovery studies were satisfactory which shows that there is no interference of excipients.

The analytical procedure developed has shown satisfactory results for all the validation parameters according to ICH guidelines. The developed method was specific as no interference of excipients was found. The developed method proved to
be sensitive, reproducible, precise, linear, accurate, robust, rugged, low amount of
detection and low amount of quantification.

The information presented in the study could be very useful in quality control,
content uniformity test, in vitro dissolution of combination of Duloxetine and
Mecobalamin drug products.

The developed method can be efficiently applied for the separation of the drugs
from its excipients and its degradation components in pharmaceutical formulation. It
can be used to check rapid and accurate drug quality during stability testing. The
method can be used in the analysis of stability samples obtained during accelerated
stability studies, as no interference was found with the degradants formed under
various stress conditions.

7.4 FUTURE WORK:

The developed stability indicating UPLC analytical method and validation of
simultaneous estimation of Rabeprazole and Domperidone; Metolazone and
Spironolactone; Duloxetine and Mecobalamin has shown to meet the acceptance
criteria of validation parameters, which could allow analysis of huge number of
samples in short period of time with less consumption of solvents. In addition, such
developed method can also be helpful in the assessment of stability of drug products
and quantification of its degradation products. Therefore I suggest that in future such
stability indicating UPLC methods should be developed for some other
multicomponent drug products that exist in pharmaceutical markets.