4. Conclusion

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4.1 Potentiometric non-aqueous titration

The potentiometry non-aqueous tritation provides rapid determination of Loratadine active drug substance. The method developed was validated and found to be accurate with relative error of 0.02%. Precision with regards to repeatability (%RSD of less than 1%) also demonstrated. Insignificant different in analyses results when the same sample was analysed by different analyst on different day demonstrated method ruggedness (intermediate precision)

4.2 RP-HPLC method

The RP-HPLC method enables simultaneously determination of Loratadine and its related substance determination in its pharmaceutical preparation has the advantage over the reported polarography method which involve derivatisation and was unable to determine the related substance or degradant of Loratadine.

The RP-HPLC method developed for Loratadine assay and related substance analysis uses conventional column material and mobile phase compositions. In the assay and related substance determination, three degradants (generated by alkali hydrolysis and H_2O_2 oxidation) and Loratadine peaks were well resolved (Figure 7b and Figure 8) from each other in just 20 minutes isocratic run.

In Loratadine bulk active drug substance impurities testing, six manufacturing impurities were successfully eluted with good resolution (Figure 9) in 30 minutes isocratic run.

The prescribed method was validated and proven to be specific, accurate robust and rugged. It also demonstrated good linear relationship in the assay and related substance range of working concentration with R^2 greater than 0.99. It is also found to be freed from fixed bias as the intercept of the linearity plot did not significantly differ from zero.

Detection limit and quantitation limit of this method were also determined and found to be 0.02μg/mL and of 0.10 μg/mL respectively which is sensitive enough to carried out assay and related substance analysis in Loratadine pharmaceutical preparation.