

3.8 Robustness

This test was performed to ascertain the capacity of the method to remain unaffected to small and deliberate variations. Robustness was performed using solutions prepared in a similar fashion as system or method precision and was evaluated based on system parameters and the recovered concentrations. (conc. in diluent = 0.05) and in plasma (conc. = 0.08 for Amlodipin, 0.1 for Glimepiride and 0.4 for Atorvastatin)

Slight variations (± 3) in wavelength have been made to the analytical method in order to evaluate and measure the capacity of the method to remain unaffected by small variation. One analytical concentration was analyzed at each level against standard solution. The RSD% was less than 2% indicating slight change in wavelength did not affect the detection parameters of the assay (Table 3.21-3.24) and (Fig. 3.13-3.17). *

Table 3.21. Effect of changing the wavelength detection by -3nm on the detection parameters

| Parameters | Amlodipine | Glimepiride | Atrovastatin |
|--------------------|------------|-------------|--------------|
| Area | 214908 | 262058 | 225750 |
| RSD% | 0.23 | 0.56 | 0.41 |
| Theoretical plates | 2600 | 4694 | 4723 |
| Asymmetry | 1.76 | 1.15 | 1.08 |

Table 3.22. Effect of changing the wavelength detection by +3nm on the detection parameters

| Parameters | Amlodipine | Glimepiride | Atrovastatin |
|--------------------|------------|-------------|--------------|
| Area | 213622 | 253252 | 233343 |
| RSD% | 0.82 | 0.61 | 0.52 |
| Theoretical plates | 2352 | 4089 | 4152 |
| Asymmetry | 1.9 | 1.19 | 1.17 |

*Refers to table(3.2)page 42