

The given results show that the assay percent under all tested conditions are within the accepted USP range 98%-102% .and all the chromatograms had a good peak shape.

Such results indicate that both drugs, esomeprazole and tadalafil are stable under the test conditions .

### **3.6 Robustness**

This test is applied to improve the method robustness by make a varying in procedure parameters within certain limit without change in results that obtained.

Robustness varies with the procedure applied. In general, it's done by varying procedure parameters and observing what effect it produces on the analyte analysis. Robustness was performed using solutions prepared in a similar fashion as system or method precision, the number of replicates (typically 3), and was evaluated based on system suitability parameters or on recovered amounts, both compared to data generated using the original method.

The following changes were done separately:

- Detector wavelength ( $\pm 3$ nm)
- pH of mobile phase ( $\pm 0.2$ ) unit of the specified value to show if there is any effect of changes in pH value.
- Mobile phase composition ( $\pm 5\%$ - $10\%$ ) acetonitrile volume.

#### **3.6.1 Robustness Regarding Wavelength ( $\pm 3$ ):**

Slight variation in wavelength had been done to the analytical method in order to evaluate and measure the capacity of the method to remain unaffected by small variations. A concentration at level 100% was analyzed at each level against a standard solution. The results are shown in table (18). The based wavelength was 285 nm, by change +3 nm wavelength, we observe the results shown in table (18) and figure (23) .