

The stability of standard solution was evaluated at room temp. 25 C° and fridge temp. 4 C° stored for 24 and 48 hours. The results obtained were compared with fresh standard solution 100% according to (ICH) guideline. For each sample preparation the concentration is 120 µg/mL of Esomeprazole and 80 µg/mL Tadalafil dissolved in mobile phase solvent. The stability results are shown for Esomeprazole and Tadalafil in tables (14,15,16, and 17) respectively for 24 and 48 hours.

2.16 Robustness Test Preparation

2.16.1 Robustness Regarding Wavelength (+3 and -3)

Sample solution prepared by the same way of sample solution preparation but the change would be in wavelength by change the UV detection reading to 282 nm with triple injections and the same procedure was applied for 288 nm with triple injections, the results obtained are shown in tables (18,19).

2.16.2 Robustness Regarding pH Changing (+0.2 and -0.2)

One homogenous Sample prepared but the change in pH was adjusted by phosphoric acid, the solution pH at the beginning as more than 6 and adjusted by adding sodium hydroxide and phosphoric acid to 6.2 and 5.8 respectively, the data obtained are shown in tables (20,21).

2.16.3 Robustness Regarding Organic Modified Composition (+5% and -5%)

This test depend on the change in organic phase by adding 5% acetonitrile to prepare mobile phase (65:35), and prepare another mobile phase solution by increasing buffer