

experienced a sudden decrease or loss of hearing after they took tadalafil or other medications that are similar to tadalafil. The hearing loss usually involved only one ear and may not get better. It is not known if the hearing loss was caused by the medication. In the case of a sudden loss of hearing, sometimes with ringing in the ears or dizziness, tadalafil or similar medications such as sildenafil (Viagra®) or vardenafil (Levitra®) should be stopped (Kubin M, *et al.*, 2003).

1.5 Validation method by Chromatographic Technique

1.5.1 HPLC Principle

High performance liquid chromatography is a separation technique that involves the injection of a small volume of liquid sample into a tube packed with tiny particles called the stationary phase where individual components of the sample are moved down the packed tube (column) with a liquid (mobile phase) forced through the column by high pressure delivered by a pump. components will be separated from one another by the column packing that involves various chemical and/or physical interactions between their molecules and the packing particles. The separated components are detected at the exit of this tube (column) by a flow-through device (detector) that measures their amount. An output from this detector is called a (HPLC chromatogram), this method is made by normal phase and reverse phase .

In normal phase, the stationary phase granted will be of high polar rigid silica, or silicabased compositions. Beside, the mobile phases are relatively nonpolar solvent, hexane, methylene chloride, or mixtures of these. Where more polar solvent has higher eluent strength, and the least polar component is eluted first. In a normal-phase column, decreasing the polarity of solvent will increase separation the components.