Solubilization of tadalafil using different cosolvents

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Background and Aims: Poor aqueous solubility is a common concern in many pharmaceutical areas, especially in preparation of liquid drug formulations and the most common method for improving the low solubility is addition of a permiscible cosolvent (cosolvency). The effects of the N-methyl-pyrrolidone (NMP), ethanol (EtOH) and propylene glycol (PG) on the solubility of tadalafil are investigated and the observed effects were compared with respect to the solubilization power of the cosolvents.

Methods: The solubility of tadalafil in water + NMP, water + EtOH and water + PG mixtures was determined at 25 °C using the shake-flask method. The saturated solutions were filtered and diluted with ethanol (96%) and assayed by a spectrophotometer at 284 nm.

Results: The solubility of tadalafil was increased with the addition of the cosolvents. NMP showed better solubilization power when compared with EtOH and PG. The measured solubility data was extended the available solubility database of pharmaceuticals in water + cosolvent mixtures.

Conclusions: NMP could be suggested as an appropriate cosolvent and enhancer for industrial applications.

Keywords: Tadalafil; Cosolvency; N-methyl-pyrrolidone; Ethanol; Propylene glycol