

## USING OF 3D-PRINTED COATING OF MATRIX TABLETS FOR PREVENTION OF ALCOHOL-INDUCED DOSE DUMPING EFFECT

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Presented *in vitro* study is primarily focused on release of the model drug tramadol hydrochloride from hydrophilic, lipophilic and dual matrix tablet in the acidic medium containing 40% alcohol. The evaluation of changes of the dissolution profiles due to the presence of alcohol was used as a suitable method for testing of the alcohol resistance of the uncoated and coated matrix tablets. As a coating material the commercial filament of polyvinyl alcohol (PVA) and the filament prepared from hypromellose by hot melt extrusion (HME) were used.

The dissolution behavior of all studied formulations was studied in the acidic dissolution medium (pH 1.2). The dissolution profiles of studied formulations in acidic medium was compared to the dissolution profiles obtained in alcohol presence (2 hrs in 40 % alcohol, then 16 hours in acidic medium).

The tablets were of cylindrical shape without facets of a diameter of 13 mm and weight of  $0.5 \pm 0.0010$  g. Dissolution testing was carried out according to the European Pharmacopoeia 9th using dissolution apparatus SOTAX AT7 Smart. Other experimental conditions: 900mL of dissolution medium, temperature  $37 \pm 0.5$  °C, 100 rpm. Released amount of tramadol hydrochloride was determined by UV/VIS spectroscopy (271 nm). All dissolution profiles were quantitatively evaluated by the non-linear regression analysis. The drug release rate constants and other kinetics parameters were evaluated.

During the dissolution tests in the alcoholic medium, it was found that the Affinisol coating was effective to prevent the dose dumping effect. Affinisol coating can be also useful for the delayed release of active substances in acidic dissolution medium.