

# STUDY OF THE SUBSTANCE SOLUBILITY EFFECT TO THE API RELEASE FROM TABLETS WITH INSOLUBLE MATRIX AGENT

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Matrix systems are commonly used to control release of drugs administrated orally. Matrix Tablets are the type of controlled drug delivery systems, which release the drug in continuous manner. Adjuvant in the matrix system forms the continuous reticulated structure (matrix) in which the APIs are distributed evenly.

To control the release of the drugs, which are having different solubility properties, the drug is dispersed in swellable hydrophilic substances, an insoluble matrix of rigid non-swellable hydrophobic materials.

For producing tablets with biconvex shape of, 8 mm diameter, the radius of curvature is 6 mm and an average weight of 200 mg had been applied for direct compression using a single-eccentric press (Korsch EC 0, Korsch, Germany). Compression force 8 KN.

API, filler and polymer have been mixed in the Mixer (Turbula T2F, Willy A. Bachofen AG, Switzerland) for 15 min., the mixture through a sieve with pores 0.5 mm has been sieved, glidants and lubricants have been added in the mixer for 4 minutes.

The insoluble polymers Ethocel Standard (Dow, USA) and Kollidon SR (BASF, Germany) have been used.

The test "Dissolution" had been conducted according to EP in unit II (VanKel 700, 7000, Varian Inc., USA) in 900 ml phosphate buffer pH 6,8 with the speed of the paddles rotation  $100 \text{ min}^{-1}$  during 12 hrs. Samples were taken through filters, optical density was measured by UV spectrophotometer (UV-2101 PC, Shimadzu Scientific Instruments Inc., USA) at a wavelength of 232 nm, which corresponds with the maximum absorption  $\text{TMZ} \cdot 2\text{HCl}$  and 269 nm, which coincides to the maximum absorption caffeine. Release of API over time was calculated as a percentage ratio to the total amount of API, which was taken as 100%.

The figure 1 shows the effect of drug solubility to the release from matrix tablet by example of matrix agent Ethocel St and Kollidon SR. Trimetazidine is a high soluble substance, caffeine is moderately soluble.

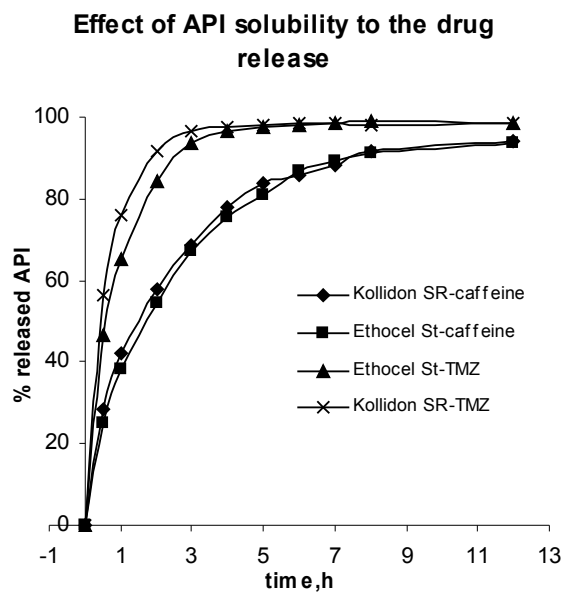


Fig. 1 Effect of API solubility to the drug release

Water solubility of active substance is an important determinant in the release of drug for hydrophobic matrix systems. There is a rapid diffusion of the active substance from the matrix. For highly soluble active substances insoluble polymers do not allow to make release extended.