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## Right filter-selection for phase separation in equilibrium solubility measurement

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### Abstract

The phase separation is a crucial step in equilibrium solubility measurements. In the standardized protocol of saturation shake-flask method, sedimentation is proposed as the safest technique. However filtration is widely used in pharma practice. In this paper the effect of the filtration on the measured equilibrium solubility results is presented. The equilibrium solubility values of four model compounds, namely diclofenac sodium, hydrochlorothiazide, papaverine hydrochloride and progesterone were determined at various pH values using the saturation shake-flask method. Two phase separation techniques (sedimentation and filtration) were applied for the separation of the solid from the saturated solution. Four membrane filters, polyvinylidene fluoride (PVDF), polyether sulfone (PES), polytetrafluoroethylene (PTFE) and nylon, as well as an analytical filter paper were investigated. The results obtained by filtration were compared with those measured by sedimentation and the distortion effect of the filter (DEF) on solubility results was expressed in %. The results showed that the filter material type is able to remarkably influence the results in solubility measurements. In several cases, the significant adsorption to the filter caused high inaccuracy in the measured concentration value, more over in some cases failed to work at all. As a main conclusion of this work, if the step of filtration is inevitable, the adsorption to the filter can be mitigated with the appropriate filter type selection what needs some experiences and knowledge about the acid-base chemistry and polar/apolar nature of the sample.

*Keywords:* Equilibrium solubility; Shake-flask method; Phase separation; Sedimentation; Filtration; Ionizable drugs

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