Developing a Method for Skin Pampa™ to Test Transdermal Patches
G. Vizseralek, B. Sinko, K. Tsinman, K. Takacs-Novak
pION Inc.

Purpose
Using the skin as absorption site presents interesting features that have facilitated the progression of transdermal drug delivery in the past decades. The transdermal patches have some fundamental advantages in therapy, however, an accepted method to measure the permeated amount of the released API's from the products has not been described yet.

Methods
The parallel artificial membrane permeability assay (PAMPA) has been recently extended by this group for the prediction of transdermal penetration (Skin PAMPA™). This commercially available system has been modified to make it suitable for transdermal patch testing. The bottom part of the Skin PAMPA Sandwich has been replaced with a deep well reservoir to provide enough space for patches to be applied in whole pieces. Direct UV spectrometry (nicotine, rivastigmine, ketoprofen) and LC-MS (fentanyl) have been used to analyze the samples.

Results
As a continuation of our project demonstrated in 2013 at AAPS, 2 more API's (rivastigmine and ketoprofen) were involved in the study beside the 2 others (nicotine and fentanyl), each applied in marketed transdermal patches. Permeation kinetic has been determined taking samples after 0.5, 1, 3, 6 and in one case even after 24 hours of incubation. The permeation vs. time profile demonstrated linear correlation in every case as expected, though the cumulative permeated amount was about 20-40% higher than indicated in the description of the patch that is estimated by the manufacturers based on the serum concentration of the API's. The higher rates can be caused by the edge effect reported by Hadgraft and co-workers previously. The figures represent the time vs. permeated amount profiles of rivastigmine and ketoprofen. In case of ketoprofen, the possible in-homogenous dispersion of the drug within the patch may influence the deviation of the results.

Conclusion
Our results suggest that Skin PAMPA system is a useful tool for transdermal patch comparisons. Results can be used for patch comparison and for ranking, therefore Skin PAMPA can provide valuable information for transdermal patch development.