Choice of USP Dissolution Apparatus for Assessing Dissolution Properties of Rivastigmine Transdermal Systems Based on the In Vitro Permeation across Human Epidermis

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**Purpose**
The present study was performed to choose an appropriate USP dissolution system for assessing the dissolution properties of rivastigmine transdermal systems (In vivo delivery rate of 4.6 mg/24 h) based on the in vitro permeation of the drug across human epidermis.

**Methods**
The dissolution testing was conducted using USP apparatus 5 (paddle over disk method, 32 °C, 50 rpm), USP apparatus 6 (rotating cylinder method, 32 °C, 100 rpm) and USP apparatus 7 (reciprocating holder method, 32°C, 30 dpm) using 20% ethanol-water as dissolution medium. In vitro drug permeation study was carried out across excised human epidermis with the same medium using an automated Franz Diffusion Cell System (32 °C, 400 rpm). The amount of rivastigmine either in dissolution samples or skin permeates was quantified by validated HPLC method.

**Results**
Steady-state permeation was observed across excised human epidermis with a flux of 54.1±3.2 µg/cm² h. The mean percent of rivastigmine dissolved at 24 h with USP apparatus 5, 6 and 7 were 91.6, 83.5 and 77.5, respectively. Regression analysis on the amount of rivastigmine permeated across human epidermis at 8, 12, 16, 20 and 24 h against the amount of rivastigmine dissolved at the same time points, per cm² of transdermal system was carried out to estimate the best correlation among the three USP dissolution apparatus. USP apparatus 6 showed higher correlation coefficient (r²= 0.9810) than USP apparatus 5 (r²= 0.9171) and USP apparatus 7 (r²= 0.9374) at the tested dissolution and in vitro permeation conditions.

**Conclusion**
Regression analysis on the amounts of rivastigmine dissolved at 8, 12, 16, 20 and 24 h showed that USP apparatus 6 best correlated with the amount of drug permeated in the in vitro permeation study across human epidermis indicating USP apparatus 6 as an apparatus of choice for dissolution testing of rivastigmine transdermal systems.

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