Terbinafine Hydrochloride Loaded Liposome Film Formulations for Onychomycosis:
Characterization and Ex Vivo Evaluation
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Purpose
The aim of this study to prepare Terbinafine hydrochloride (TBF-HCl) loaded liposome included film formulations for ungual therapy of onychomycosis. Ex-vivo nail permeation studies was performed with these formulations to investigate accumulation of TBF-HCl on nail plate.

Methods
The thin film hydration method was used to prepare the liposomal suspensions. Formulations were characterized in terms of the z-average mean (Z-size), polydispersity (PI) and zeta potential (ζ (mV), the entrapment efficiency (EE), the pH. Film former polymer was dispersed with TBF-HCl loaded liposome suspensions to perform film formulations. Propylene glycol also was added to mixture and heated at 30°C and water content evaporated to form film formulation. Prepared film formulations were analysis macroscopically and weight, bioadhesive properties and breakable of films were tested. Specially modified Franz diffusion cells and human cadaver nail samples were used for ex-vivo permeation experiment. Samples were analyzed by validated method of HPLC. TBF-HCl was extracted from pulverized nails. After centrifugation amount of drug was measured by HPLC. The amount of TBF-HCl remained in the nail plate was presented as a percentage of the drug concentration in donor phase at the beginning of experiment.

Results
The results of characterization of liposome formulations with different concentration of lipid:drug ratio (L1-L2) were summarise in Table 1. The film formulations were prepared with selected liposome formulations. Characterization of film formulations was shown in Table 2.

After permeation experiment no drug determined from receptor phase of Franz diffusion cells. By the way; TBF-HCl accumulated in the nail plate during ten days. The amount of TBF-HCl accumulated in the nails during experiment was measured by pulverization of nails. The percentage of accumulated drug in the nail plate was found % 11.46 and % 8.50 for F1 and F2 formulation, respectively.

Conclusion
As a conclusion, it was aimed to prepare transungual film formulation of terbinafine hydrochloride as an alternative systemic application. It was found that this film formulation will be a good alternative to systemic therapy. Liposome pullulan film formulation is effective and has easy application to the nail plate.