



Comparison of Impurity Profiles of Lipiblock® vs. Orlistat using HPLC and LC-MS/MS

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SUMMARY. Comparative HPLC-UV and LC-MS/MS studies of impurity profiles of a reference sample (Xenical®, F. Hoffmann–La Roche Ltd., Switzerland) vs. generic (Lipiblock®, EMS–Sigma Pharma, a generic drug) were carried out with ethanol extracts of commercial samples. The generic formulation contained higher levels of common impurities as well as a considerable number of impurities not found in the reference product. The detected impurity profile of Lipiblock® revealed that it most likely is based on fermentation. Since the effect of the impurities is unknown, at this point fully synthetic Xenical® appears to offer a better safety margin than Lipiblock® which, however, compares quite well to other generic formulations.

KEY WORDS: Generics, HPLC-MS/MS, HPLC-UV, Orlistat.

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