

Publication**Pharmaceutical quality of nine generic orlistat products compared with Xenical(R)****JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)****ID** 433261**Author(s)** Taylor, Peter W.; Arnet, Isabelle; Fischer, Anton; Simpson, Iain N.**Author(s) at UniBasel** [Arnet, Isabelle](#) ;**Year** 2010**Title** Pharmaceutical quality of nine generic orlistat products compared with Xenical(R)**Journal** Obesity Facts**Volume** 3**Number** 4**Pages / Article-Number** 231-7**Keywords** Orlistat, Xenical, Pharmaceutical quality, Generics

To compare the pharmaceutical quality of Xenical (chemically produced orlistat) with nine generic products, each produced by fermentation processes.; Xenical 120 mg capsules (Roche, Basel, Switzerland) were used as reference material. Generic products were from India, Malaysia, Argentina, Philippines, Uruguay, and Taiwan. Colour, melting temperature, crystalline form, particle size, capsule fill mass, active pharmaceutical ingredient content, amount of impurities, and dissolution were compared. Standard physical and chemical laboratory tests were those developed by Roche for Xenical.; All nine generic products failed the Xenical specifications in four or more tests, and two generic products failed in seven tests. A failure common to all generic products was the amount of impurities present, mostly due to different by-products, including side-chain homologues not present in Xenical. Some impurities were unidentified. Two generic products tested failed the dissolution test, one product formed a capsule-shaped agglomerate on storage and resulted in poor ($\geq 15\%$) dissolution. Six generic products were powder formulations.; All tested generic orlistat products were pharmaceutically inferior to Xenical. The high levels of impurities in generic orlistat products are a major safety and tolerability concern.

Publisher Karger Publishers**ISSN/ISBN** 1662-4025 ; 1662-4033**edoc-URL** <http://edoc.unibas.ch/dok/A5841041>**Full Text on edoc** Available;**Digital Object Identifier DOI** 10.1159/000319450**PubMed ID** <http://www.ncbi.nlm.nih.gov/pubmed/20823686>**ISI-Number** WOS:000281664200004**Document type (ISI)** Journal Article