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# A single-blind, randomized, two-part, 6-way cross-over study to investigate the individual bioequivalence of gabapentin 800 mg tablets as Neurontin® 800 mg and its generic Gabasandoz® in healthy volunteers

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The first aim was to investigate switchability of Neurontin® 800 mg (2x Batch 'A') and Gabasandoz® 800 mg (2x Batch 'A') using the individual bioequivalence (IBE) approach. The second was to investigate switchability in a more real-life situation by including two different batches of each product (Neurontin® Batch 'B', Gabasandoz® Batch 'B'). This study was conducted in 30 healthy subjects, of whom 29 received 6 times - in randomized order - a single dose of 800 mg Neurontin® (Batch 'A' or 'B') or 800 mg Gabasandoz® (Batch 'A' or 'B'). Serum concentrations of gabapentin up to 36 hours after dosing were determined using a validated UPLC-MS-MS method. According to the FDA, IBE can be established if the 95% upper-confidence bound (UCB) of η (i.e., a function of different variance terms) is lower than the IBE limit θ, which is 2.5. For AUC(0-inf) and Cmax, η and its 95% UCB were calculated. η was 0.58 and 0.19 for AUC(0-inf) and Cmax, respectively, and the 95% UCB was 1.32 and 0.63 (both p-value <0.001), respectively. When including data on batch 'B' of Neurontin® and Gabasandoz®, η was 0.46 and -0.08 for AUC(0-inf) and Cmax, respectively. The 95% UCB was 1.20 and 0.40, respectively (both p-value <0.001). This study indicates that Neurontin® 800 mg (Batch 'A') and Gabasandoz® 800 mg (Batch 'A') are individual bioequivalent and switchable in clinical practice. When simulating a more real-life situation by expanding the experimental design with an additional batch of each product (Batch 'B'), both brands still met the switchability criteria.

## Biography

Elien Van Bever is a pharmacist, clinical pharmacologist-in-training and PhD-student at the Ghent University, Ghent, Belgium. She started her PhD in 2011, which involves topics such as generic prescribing and substitution, individual bio-equivalence and switchability of medicines, and prescribing regulation.

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