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Effect of formulation development and API characteristics on fast dissolving dosage forms bioequivalence studies

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Fast Dissolving Dosage Forms represent excellent opportunities for life cycle management to the pharmaceutical companies. They have many advantages like ease of swallowing, administration without water, quick onset of action for improving both patient convenience and compliance as benefits for patient; extended life cycle, product differentiation, patent protection. But there are some challenges for formulation development studies for the generic companies. In the sense of generic companies, developing a Fast Dissolving Formulation version of an existing immediate-release product means that the two formulations must be bioequivalent and this can be challenging for *in-vivo* studies especially if the method of taste masking retards the dissolution rate of the active ingredient after disintegration. On the other hand, what will be the effects on the BE studies if the API has significant degree of buccal or sublingual absorption occurs in this case?

Biography

Gulay Yelken Demirel completed his Bachelor's degree in Chemistry from University of Gazi (Ankara, Turkey) followed by a Master's degree at Medicinal and Pharmaceutical Chemistry (faculty of pharmacy) from same university. She is also a Turkish Patent Attorney. She has nine years experience in R&D department of generic pharmaceutical companies. She worked at the Pharmaceutical Technology Department and gained experience in pre-formulation and formulation studies, new combination and techniques for formulation development studies, OTC and herbal drugs formulations, bioequivalence batches preparation and *in-vitro* studies, drug product dossier preparing with main focus on generic drugs for different market applications. Presently, she owns the R&D Project Group Executive position at Sanovel Pharmaceuticals. She has several published papers in the academic areas and over 35 patents & patent applications in the industrial areas on pharmaceutical dosage forms.

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