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Fast dissolving drug delivery systems

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Fast-dissolving formulations represent excellent opportunities for life cycle management to the pharmaceutical companies. Fast dissolving technologies 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 as benefits for pharmaceutical companies. But there are some challenges for formulation development studies like taste-masking, disintegration time, moisture sensitivity, friability, packaging and intellectual property issues especially for the generic companies. The technologies are under patent protection like Zydis®, Flashtab®, OraSolv® and DuraSolv™, WOWTAB®. One of major issues is taste-masking problem, may be overcome with using cyclodextrins, polymer coating, flavoring&sweetening agent, microencapsulation techniques. There are some modified excipients for providing both taste-masking and productability properities in the formulation like Ludiflash® and Pharmaburst®. From the analytical development point of view there are a number of different methods from conventional dosage forms which are determined in the Pharmacopoeias. And for comparison and assessment of taste masking, electronic tongue may be a good opportunity which was developed by Alpha M.O.S. In the sense of generic companies, developing a fast dissolving tablet 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. What about the future of fast dissolving technologies? Orally disintegrating extended Release (ODT-ER) dosage forms are providing all of the benefits of these two drug delivery technologies in a single pharmaceutical product. And oral rapid films also may be a good alternative especially for the OTC market.

Biography

Gulay Yelken Demirel has degree in Department of Chemistry from University of Gazi (Ankara, Turkey) followed by a Master degree at Medicinal and Pharmaceutical Chemistry (faculty of pharmacy) from same University. She is also a Turkish Patent Attorney. She has eight years experience in R&D department of generic pharmaceutical companies. She worked as formulation scientist at the Pharmaceutical Technology Department of Nobel Pharmaceuticals. She gained experience in pre-formulation and formulation studies, new combination and techniques for formulation development studies, process validation, scale-up, bio-equivalance batches preparation, drug product dossier preparing with main focus on generic drugs. Presently, she owns the R&D Senior Specialist position at Sanovel Pharmaceuticals with development and validation of stability indicated analytical methods, stability tests, in-vitro studies of bio-equivalence batches, OTC and herbal drugs formulations, patent applications in addition to her skills mentioned before. She has several published papers in the academic areas and over 30 patents & patent applications in the industrial areas on oral dosage forms.

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