

Buccal Drug Delivery Systems: Opportunities and Challenges in Buccal, Sublingual Films, Tablets & Sprays – Detailed Analysis on Technologies and Pipeline Development

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Abstracts

Within the oral mucosal cavity, the buccal region offers an attractive route of administration for systemic drug delivery. The mucosa has a rich blood supply and it is relatively permeable. The buccal mucosa offers several advantages for controlled drug delivery for extended periods of time. The mucosa is well supplied with both vascular and lymphatic drainage and first-pass metabolism in the liver and pre-systemic elimination in the gastrointestinal tract are avoided. The area is well suited for a retentive device and appears to be acceptable to the patient. With the right dosage form design and formulation, the permeability and the local environment of the mucosa can be controlled and manipulated in order to accommodate drug permeation. Buccal drug delivery is a promising area for continued research with the aim of systemic delivery of orally inefficient drugs as well as a feasible and attractive alternative for non-invasive delivery of potent peptide and protein drug molecules. In 2014, sales of Suboxone sublingual film totalled approximately \$1.3 billion in the U.S. while the total market grew to more than \$1.7 billion, driven by a 11 percent increase in prescriptions. In 2014, Bunavail buccal film has received US approval which has similar bioavailability of suboxone with half of the dose of buprenorphine.

Other than drugs used for local actions (antifungal, antiviral), generally controlled substances like buprenorphine, naloxone and fentanyl are preferred to release the drug through buccal formulations. However, testosterone (striant) to treat low testosterone levels in men also approved through use of buccal system of delivery. In the US, drugs such as Isosorbide dinitrate, ergoloid delivered sublingually have been discontinued and nitroglycerin has been replaced with sublingual metered spray. Ergomar (ergotamine

tartarate) marketed by Rosedale therapeutics is the only sublingual tablets available in the US market, priced \$15 per pill. Subsys (fentanyl) developed by Insys therapeutics was the recent sublingual spray approved in the US for the treatment of breakthrough cancer pain.

Global pharma companies such as Biodelivery Sciences, Bioalliance pharma (Onexo), Meda pharma, Orexo, Generex, Teijin are actively involved in developing oral mucoadhesive buccal delivery systems while sublingual technology have been used by Teva, Sun pharma, Grunenthal, Neurax, Angelini, Sandoz, Ethypharm, Arrow generics, Purdue and Actavis pharma. Sublingual spray technology have been employed by the companies such as Insys therapeutics, Perrigo, Mist pharm, Regency, Novadel, Generex, GW Pharma and Pohl Boskamp in developing potential drugs for the patients.

Ease of administration and better compliance offered by delivering through buccal route offers advantages for patients and physicians over other Invasive route and oral ingestion will drive the market further in positive directions going forward. Novel buccal delivery such as soluble thin films, mucoadhesive films and rapidmist spray offers newer route of delivery for the generics that has lesser patients compliances.

This report will provide detailed analysis on buccal delivery systems in broader pharma market in finding companies and technologies and complexities involved in developing this unique high potential delivery system

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 Soluleaves
 Wafertab
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 Micap

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Angelini
Applied Pharma Research
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Barr
Biodelivery Sciences
Blue fish

Cynapsus Pharma
Ethypharm
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