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Orally Disintegrating Tablet and Film Technologies

FIFTH EDITION

TECHNOLOGIES, PRODUCTS, & MARKET ANALYSIS

About Technology Catalysts International

Technology Catalysts International (TCI) was founded in 1979 to provide consulting services that satisfy the technology transfer and business research needs of industry. We specialize in technology transfer, technology assessment, and technology portfolio management. The firm is headquartered in Falls Church, Virginia; a suburb of Washington, D.C. Our global network includes offices in Japan, India, China, Argentina, the United Kingdom, Germany and the Czech Republic.

Our research staff is comprised of professionals with backgrounds in a variety of technical disciplines, with additional expertise in international marketing, licensing, finance and business development. They are skilled in providing clients with strategically important competitive information worldwide. The breadth of our experience assures clients of high quality, actionable information, and complete coverage on topics of interest.

TCI's core consulting services are based on continuous monitoring of technological product development activities on a global basis. The company provides consulting and technology transfer services to leading product developers and manufacturers in North and South America, Europe, and Asia. Our client base consists of small, medium, and large corporations.

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Report Summary

Orally disintegrating tablets (ODT) and fast dissolving (or fast melt) dosage forms have continued to expand in sales and number of launched products as dysphagia, patient compliance, and convenience issues are addressed for pharmaceuticals that have been traditionally administered as oral solid dosages. In addition, the fast melt market maintains its strength as an area that is easy to enter for either brand or generic companies with access to ODT technology.

As a result, over 200 branded and generic products have now been commercialized in ODT formulations. Combined, these ODT products (both prescription and OTC) are approaching ten percent of the global oral drug delivery market with 2006 revenues of over $3.8 billion. Although the ODT market growth rate has slowed when compared to previous years, products collectively increased 20 percent in value from 2005. Based on the current global growth trends, the ODT market is set to approach revenues of $8 billion by 2010.

The ODT market appears to have stabilized with regards to regional dominance. Japan now maintains a 37 percent market share of global ODT sales, the US has 30 percent, and Europe has 27 percent. However, the geographic dominance of the oral thin film segment is quite different. Nearly all of these products' sales (excluding breath fresheners) are currently derived from the North American market. This scenario will likely change, however, as more products are introduced in Europe and Asia. Between 2003 and 2007, more than 50 different oral thin film brands were launched in the US and Canada. New products have been introduced steadily at a rate of about 10 new SKUs per year. Oral thin films continue to be viewed as a replacement technology for ODT products to provide a higher barrier to generic entry and product differentiation to OTC brands.

As pharmaceutical companies begin to develop orally disintegrating products, they have many choices regarding the formulation technology. Proprietary technologies from drug delivery/specialty pharmaceutical companies can be licensed and/or products co-developed. Alternatively, disintegrant excipients can be purchased directly from third party manufacturers for in-house ODT development. Increased generic competition is expected to further expand the ODT market, resulting in increased used of specialty disintegrant excipients.

The Market, Pipelines, LCM Candidates, Opportunities

This report covers the current market for ODTs/oral thin films and future forecasts are based on active pipeline products, life cycle management drug candidates, and licensing and business development opportunities. There are nearly seventy companies with ODT and thin film technology described in detail in this report that are actively out-licensing molecules and platforms in early and late stage development.

New to the Fifth Edition:

- Excipient technologies designed for disintegrating tablet/film preparations
- ANDA suitability petitions filed for oral thin films
- Erosion of US ODT brand sales by generics
- Expanded list of launched oral thin film products to include Asian formulators
- Alternative applications for thin film technologies including topical/transmucosal, veterinary, and consumer
- Updated drug candidates for ODTs based on LCM
- Strategies for taste masking ODTs with nearly twenty technologies profiled
- Information on the first ODT vaccine
- Update on Paragraph IV lawsuits of generic ODTs
- Details on additional ODT and oral thin film technologies not covered in the fourth edition

Key Information Presented

Market Analysis

- Orally Disintegrating Tablets:
  - Market growth from 2002-2007
  - Sales for leading ODTs in 2006
  - Market share by therapeutic category
  - Market share by region
  - Market forecast with updated product pipeline
- Oral Thin Films:
  - Current USA market for oral thin films
  - Sales comparison of an oral thin film to ODT product form 2004-2006
  - Market forecast with updated product pipeline

Product Introductions

- ODT products approved in 2006 and 2007 in the US, Europe, and Japan
- Oral thin film OTC drugs launched in USA/EU from 2003 to 2007
- Oral thin film nutraceuticals/vitamins launched in North America from 2003-2007

Technology Licensing Opportunities

- Detailed Profiles Sorted by Technology Type
- Technologies From North America, Europe, and Asia
- Patent and Pipeline Information for Each Technology
- Contact Information to Initiate Licensing Agreements

Orally Disintegrating Tablet and Film Technologies

5TH EDITION

Technologies, Products, & Market Analysis

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