



Worldwide contacts for additional information

World Headquarters

Ajay Rastogi
Vice President
Technology Catalysts International Corporation
605 Park Avenue
Falls Church, VA 22046 USA
Telephone: (703) 531-0257
Facsimile: (703) 237-0042
E-mail: arastogi@technology-catalysts.com
Internet: www.technology-catalysts.com

Europe

Graham L. Crawford, MSc
Managing Director
Technology Catalysts International UK
Blacksmiths
Clifton Road
Newton Blossomville
Bedford MK43 8AS UK
Telephone: +44 1234 881583
Facsimile: +44 1234 881027
E-mail: gcrawford@technology-catalysts.com

Gerhard Wallenwein, Ph.D.
Managing Director
Laves Chemie Consulting
Koenigsteiner Strasse 80
D-65812 Bad Soden, Germany
Telephone: +49 6196 62057
Facsimile: +49 6196 27837
E-mail: laveschemie@t-online.de
Internet: www.laveschemie.de

Jana Kuhnlova
Managing Director
Inventia s.r.o.
Na Belidle 3
150 00 Praha 5 - Smichov, Czech Republic
Telephone: +420 2 22247484
Facsimile: +420 2 24218645
E-mail: kuhnlova@inventia.eu
Internet: www.inventia.cz

Milos Hraba
Manager NBD
Inventia s.r.o.
Na Belidle 3
150 00 Praha 5 - Smichov, Czech Republic
Telephone: +420 2 22247484
Facsimile: +420 2 24218645
E-mail: hraba@inventia.eu

Asia

Sansei Oka
Japanese Business Representative
Technology Catalysts International
4-18-11-101, Takada-Higashi
Kohoku-Ku, Yokohama 223-0065, Japan
Telephone: +81 45 543 5578
E-mail: soka@technology-catalysts.com

Mitsuhisa Tamura
Senior Research Associate
Sumika Technical Information Service Inc.
15 Fl., Tokyo Sumitomo Twin Bldg. (East)
27-1, Shinkawa 4-chome
Chuo-ku, Tokyo 104-0033, Japan
Telephone: +81 3 5543 5875
Facsimile: +81 3 5543 5945
E-mail: mitsuhisa-tamura@ya.sumitomo-chem.co.jp
Internet: www.stis.co.jp

Don Ki Kim
President & CEO, Pharmacist
Global Damon Pharma
Seoul
Korea
Telephone: +82 2 3673-2367
Facsimile: +82 2 3673-2369
E-mail: dlkim@gdp.co.kr

Mr. Jaison Abraham
General Manager
TCI India
Level 4, Dynasty, 'A' Wing
Andheri-Kurla Road
Andheri East
Mumbai 400 069, India
Telephone: +91-22-4030 9499
Facsimile: +91-22-4030 9199
Mobile: +91-98-1932 8598
E-mail: jaison@zenara.com

Mr. R.K. Gupta
Managing Director
Industrial Development Services Pvt. Ltd.
M-1 Kanchenjunga
18 Barakhamba Road
New Delhi 110 001, India
Telephone: +91-11- 2 331 2287; 2 331 4714
Facsimile: +91-11-23738227
E-mail: ids@del2.vsnl.net.in
Internet: www.ids-india.org

South America

Carlos A. Massone M.D.
President
Qualia S.A.
Jeronimo Salguero 2533, Piso 12 "A"
1425, Buenos Aires, Argentina
Telephone: +54 11 4807 3433
Facsimile: +54 11 4807 2933
E-mail: carlos.massone@qualia.com.ar
Internet: www.qualia.com.ar

ORALLY DISINTEGRATING TABLET AND FILM TECHNOLOGIES

SIXTH 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, Korea, 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. We provide 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.

For more information on our services and capabilities, please visit TCI's website at:

www.technology-catalysts.com

Visit TCI's website at:

www.technology-catalysts.com

Report Summary

Orally disintegrating and fast-dissolving (or fast melt) dosage forms – tablets (ODT) and oral thin films (OTF) – have continued to expand as dysphagia, patient compliance, and consumer convenience issues are addressed by pharmaceuticals that have been traditionally administered as oral solid dosages. In addition, the market for rapidly dissolving formulations maintains its strength as an innovative concept for either brand or generic companies with access to dissolving technology.

As a result, the combined US, EU and Japanese ODT market has doubled in size over the past four years to surpass \$6.4 billion in 2009. Increased generic competition has further expanded the ODT market volume. Consequently, the number of commercial OTC and Rx ODT products has ballooned to over 450. This can be attributed to the rapid genericization of many products by a large number of Gx companies. Based on upward global growth trends of the past decade, the ODT market could produce revenues of \$13 billion by 2015.

While there have been more than 80 oral thin film brands launched in North America since 2003, the market remains limited when compared to ODTs. However, the OTF sector is well-positioned for future growth. New OTC films are being commercialized in the US to expand into lucrative markets (e.g. pain management and motion sickness). More importantly, prescription OTFs have now been approved in all three major regions (US, EU, and Japan). These approved Rx films, along with several key molecules in the OTF pipelines, have potential to cannibalize other oral dosage forms of the same drugs. If additional Rx products continue to be commercialized and truly novel OTFs are developed, the value of the overall oral thin film market will grow significantly.

As companies begin to develop orally disintegrating products, they have many choices regarding the formulation technology and tastemasking. Proprietary technologies from drug delivery and specialty pharmaceutical companies can be utilized. Alternatively, disintegrant excipients and readily available flavors can be purchased directly from third party manufacturers for in-house ODT development.

The Market, Pipeline Candidates, Opportunities

This report covers the current market for ODTs/oral thin films and future forecasts based on active pipeline products, life cycle management drug candidates, and licensing and business development opportunities. There are 90 companies with ODT and thin film technology described in detail in this report; many are actively out-licensing molecules and platforms in early and late stage development. DDS technology providers also interested in co-developing and/or manufacturing new oral fast-dissolving products are profiled.

New to the Sixth Edition:

- Details on formulation and manufacturing techniques for both ODT and OTF products
- Information on oral thin film packaging and converting
- Overview of US ODT Suitability Petitions and Authorized Generic products
- Generic ODT competition in Japan
- Information on the first prescription thin films in the US, EU, and Japan
- Profiles on 20+ additional ODT and oral thin film technologies not covered in the fifth edition
- US FDA Guidance for ODTs
- Appendix outlining all ODTs that have been commercialized (branded and generic)

Key Information Presented

Market Analysis

- Orally Disintegrating Tablets:
 - Market revenue growth from 2003-2009
 - Sales for leading Rx ODTs in 2009
 - Unit sales growth from 2005-2009
 - Market share by therapeutic category
 - Market share and growth shift by region
 - Brand erosion by generics and market forecast
- Oral Thin Films:
 - US OTC oral thin film sales from 2007-2009
 - Sales comparison of leading OTF brand to ODT counterpart from 2004-2009
 - FDA actions and market changes that have affected OTF growth
 - Market forecast with updated product pipeline

Product Introductions

- Recent ODT products approved from 2008-10 in the US
- ODT products launched in Europe and Japan, 2008-2009
- Oral thin film OTC drugs launched in US/EU from 2003-2009
- Oral thin film nutraceuticals/vitamins launched in North America from 2003-2009
- Prescription OTFs approved in US, EU, and Japan

Technology Licensing Opportunities

- Detailed profiles sorted by technology type:
 - ODT technologies: 45 profiles
 - OTF technologies: 45 profiles
 - Tastemasking for ODT/OTF: 26 profiles
 - Excipient platforms for ODT/OTF: 17 profiles
- 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

SIXTH EDITION

Technologies, Products, & Market Analysis

ORDER FORM

Per Copy (Paper Copy PDF Copy) \$4,950

Extra paper copies x _____ \$500 ea.

Note: All prices are U.S. dollars

Total Amount Due: _____

Shipping/Purchase Information:

Name _____

Title _____

Company _____

Address _____

Telephone _____

Facsimile _____

Email _____

Signature _____

Date _____

Credit Card (MC Visa Amex)

Card Number _____

Expiration Date _____ Security code (3 or 4 digits) _____

Check enclosed, made payable to Technology Catalysts International

Send invoice to the address above

Wire transfer: please contact TCI directly

Mail, Fax, or Phone your order to:

Ajay Rastogi
Vice President
Technology Catalysts International
605 Park Avenue, Falls Church, VA 22046, USA
Telephone: (703) 531-0257
Facsimile: (703) 237-0042
E-mail: arastogi@technology-catalysts.com