

PROSOLV[®] ODT G2

Orally Disintegrating Tablet Matrix



A Tasteful New Design in Solid Dosage Forms

Offering Advantages for:

- **Formulation Development**
- **Manufacturing Ease**
- **Business Simplicity**
- **Patient Compliance**

PROSOLV[®] ODT G2

Orally Disintegrating Excipient Matrix

What is PROSOLV[®] ODT G2 ?

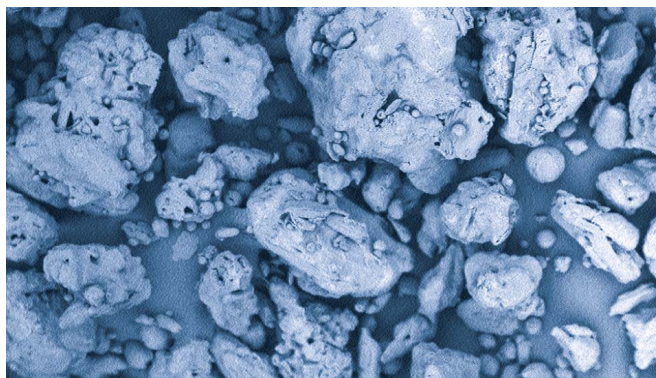
PROSOLV[®] ODT G2 is a high functionality excipient for orally disintegrating tablet formulation, development, and manufacture. It provides the functional performance needed for today's orally disintegrating tablet formulation challenges and offers a creamy, smooth, cool mouth feel.

Composition:

- Microcrystalline cellulose
- Colloidal silicon dioxide
- Mannitol
- Fructose
- Crospovidone

Physical Properties

- Free flowing, co-processed excipient
- White to nearly white in color
- Bulk density: 0.45 – 0.65 g/mL
- Average particle size: 40 – 80 μm
- Excellent flowability, leading to greater productivity
- Highly compactible
- Good mouth feel, resulting in excellent patient compliance
- Rapidly hydrating, allowing faster disintegration



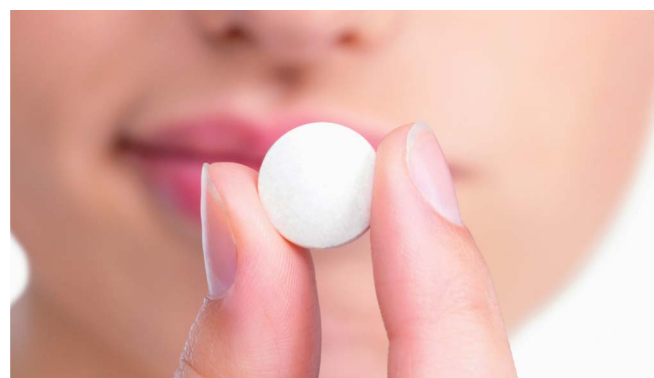
PROSOLV[®] ODT G2 matrix

Applications

PROSOLV[®] ODT G2 is used for the development and manufacture of orally disintegrating tablets, allowing the discrete and convenient administration of active ingredients without water, resulting in high patient compliance.

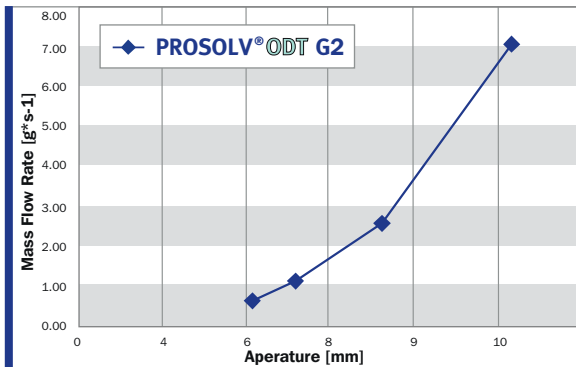
Benefits

- Simple to use
- Fast and freely flowing
- Smooth and creamy mouthfeel
- Superior compaction profile compared to other matrices
- Excellent blending characteristics for improved content uniformity
- Requires no additional binders or disintegrants
- Royalty-free
- License-free
- Faster time-to-market
- Directly compressible for simple manufacture



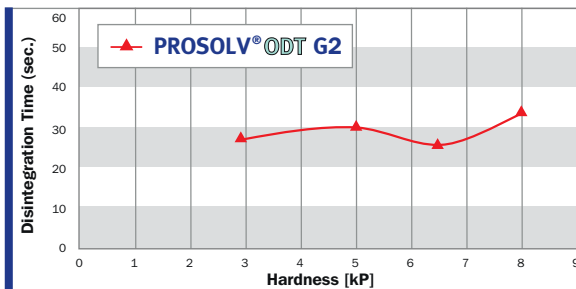
Benefit your Customers and Operations with PROSOLV® ODT G2

Mass Flow Rate



Superior flow for high speed tableting

In Vitro Tablet Disintegration



Consistent disintegration and quality
Placebo with 99.5 % PROSOLV® ODT G2

Example Formulation

Tablet Components	Amount per Tablet
Piroxicam	10.00
PROSOLV® ODT G2	88.75
Cream Flavor	0.25
Vanilla Flavor	0.25
PRUV® Sodium Stearyl Fumarate	0.75

Tablet Components	Amount per Tablet
Weight	100.0 mg
Size	0.2500 ^l SC round
Hardness	3.5 kP
Friability	0.0 %
Disintegration Time (USP)	27 sec
Weight Variation (%RSD)	0.8

Accelerated Stability

Characteristic	Initial	6 month
Tablet Disintegration (sec, 4 kN)	28	32
% Moisture (Karl Fischer)	0.72	0.9
Tablet Hardness (KP, 4 kN force)	4.2	4
Assay for Sugars & Sugar Alcohol (%)	4.8/66.5	4.8/66.2
Presence of Impurity Peaks	neg	neg

Storage conditions: 40 °C / 70 % r.h. according to the ICH Q1A guideline

Packaging, Samples and Storage

Storage

Store in well closed container.
Protect from excessive heat and moisture.

Packaging

25 kg carton, double PE liner;
Drums available upon request

Pallet-container

500 kg (cartons)

Sample Sizes

Available in 2 kg containers

Case Studies

Case studies and formulation examples are available upon request. Please contact your sales rep for more information or visit www.jrspharma.com.

Disclaimer:

The information provided in this brochure is based on thorough research and is believed to be completely reliable. Application suggestions are given to assist our customers, but are for guidance only. Circumstances in which our material is used vary and are beyond our control. Therefore, we cannot assume any responsibility for risks or liabilities, which may result from the use of this technical advice.





Bringing Health Science to Life

Products and Services

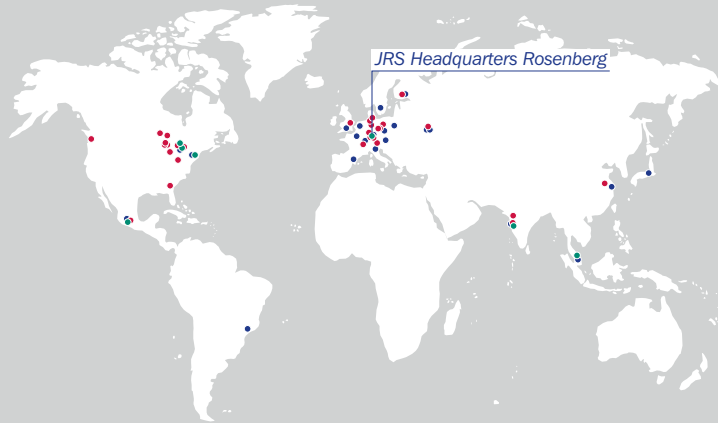
Excipients

- Family of High Functionality Excipients
- Binders
- Functional Fillers
- Lubricants
- Thickeners+Stabilizers
- Carriers
- Superdisintegrants

Coatings

Biopharmaceuticals

- Contract R+D
- Manufacturing



- Production Sites
- JRS Sales Companies
- R+D and Application Technology Centers

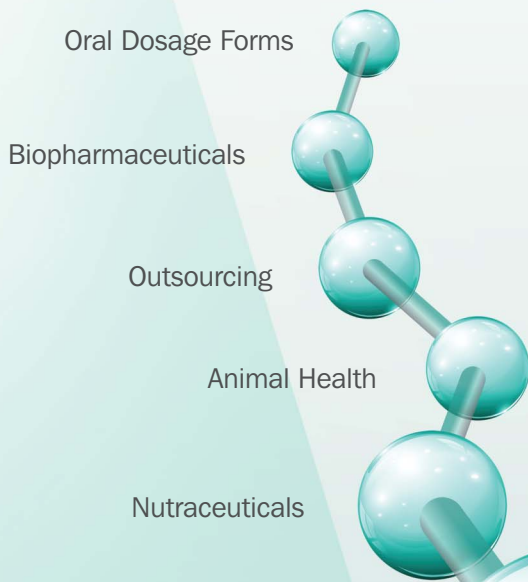


www.project-pharmaceutics.com



www.celonic.com

Customers' Needs



Customers' Values

