Patent of the Frosta® Technology

United States Patent
Fu et al.

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HIGHLY PLASTIC GRANULES FOR MAKING FAST MELTING TABLETS

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FOREIGN PATENT DOCUMENTS
WO 95/34293 A1 12/1995

OTHER PUBLICATIONS

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ABSTRACT
## Competing Technologies

<table>
<thead>
<tr>
<th>Commercial Product</th>
<th>Technology</th>
<th>Disadvantages/Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zydis® (Cardinal Health)</td>
<td>Freeze drying</td>
<td>High cost</td>
</tr>
<tr>
<td>Quicksolv® (Janssen)</td>
<td>Freeze drying</td>
<td>Very weak tablets</td>
</tr>
<tr>
<td>OraSolv®</td>
<td>Effervescent mixture</td>
<td>Weak tablets, Special PakSolv</td>
</tr>
<tr>
<td>DuraSolv® (Cima)</td>
<td>Nondirect compressible sugar</td>
<td>Slow disintegration</td>
</tr>
<tr>
<td>WOWTAB® (Yamanouchi)</td>
<td>Moisture treatment process</td>
<td>Difficult processing steps</td>
</tr>
<tr>
<td></td>
<td>High &amp; Low moldability sugars</td>
<td>Slow disintegration</td>
</tr>
<tr>
<td>Ziplets™ (Eurand)</td>
<td>Water-insoluble inorganic particles</td>
<td>Not complete dissolution</td>
</tr>
<tr>
<td>AdvaTab™</td>
<td>External lubrication system</td>
<td>Not efficient process</td>
</tr>
<tr>
<td>Flashtab® (Ethypharm)</td>
<td>Multi-particulate tablet</td>
<td>Slow disintegration</td>
</tr>
<tr>
<td>FlashDose® (Biovail)</td>
<td>Sachet/floss formulation</td>
<td>Difficult to formulate</td>
</tr>
<tr>
<td>OraQuick™ (KV)</td>
<td>Sintering at 50 °C for 50 min</td>
<td>Difficult process</td>
</tr>
<tr>
<td>Pharmburst™ (SPI Pharma)</td>
<td>Dry blending of special excipients</td>
<td>Slow disintegration</td>
</tr>
</tbody>
</table>
Main Concept of Frosta® Formulation

The same unit processes as making conventional tablets

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Drug, Diluent, Dry binder

Wet Granulation

Highly plastic granules
Maintaining the porous structure of granules during compression

Frosta® Tablets
Tableting
Blending
Internal Structure of a Frosta® Tablet

Presence of pores between granules for fast absorption of water, leading to fast dissolution of the tablet

(White arrows show 2 example pores)
Advantages of Frosta® Tablets

- **Fast melting**
  - Melt like frost
  - Melt in 5-40 seconds
  - Good mouth feel

- **Durable**
  - High mechanical strength
  - Very low friability (<1%)
  - Multi-tablet packaging

- **Economical**
  - Simple wet granulation
  - Standard tablet machine
  - Easy scale-up
  - Low cost

- **Versatile**
  - Drugs
  - Nutritional supplements

- **Unique**
  - All advantages in one formulation
Frosta® Fast Melting Tablets

Combined benefits of **solid dosage form & liquid formulation**

Frosta

akinainc.com/frosta.html
Frosta® Nutritional Formulations

Glucose
Calcium citrate, Calcium carbonate (Antacid)
Chondroitin Sulfate/Glucosamine
Vitamin B12/Folic Acid
Multivitamin
Melatonin

A fast-melting Frosta
4 g glucose tablet.
15% more porous volume.
The same price.

A slow dissolving
4 g glucose tablet
on the market.
Large-Dose Formulations

Frosta 500 mg Acetaminophen
The same size as meltaways
Dissolving time < 30 sec

Only 160 mg
Dissolving time > 1 min
Frosta® Tablet Examples

Drugs
Cetirizine, Loratadine, Tramadol, Ondansetron, Venlafaxine, Risperidone, Simvastatin, Donepezil

Sustained-Release Formulations
Dextromethorphan (12-hour release)
Paroxetine (24-hour release)
Tamsulosin (24-hour release)

Large-Dose Formulations
Acetaminophen
Fexofenadine
Multivitamin

Nutraceuticals
Frosta® Toothpaste Tablets

An Alternative to Conventional Toothpaste