J.T.Baker® PanExcea™ MC200G Performance Excipient for Orally Disintegrating Tablets: General Use Guidelines

Introduction

J.T.Baker® PanExcea™ MC200G performance excipient from Avantor™ Performance Materials is designed to provide good compressibility, excellent flow properties and fast disintegration and dispersibility in your Orally Disintegrating Tablet (ODT) drug application. PanExcea MC200G performance excipient’s flexibility allows it to be used in developing ODT formulations consisting of low to high dose drugs. It also is compatible with and was designed for use with most other excipients commonly used in the preparation of tablet dosage forms. These excipients can be used to optimize the tableting process and to provide the desired properties of taste and texture to impart a pleasant mouth feel. The generalized formulae based on the dose of the Active Pharmaceutical Ingredient (API) are shown below.

| TABLE 1 Low Dose Drug Orally Disintegrating Tablets |
|-----------------------------|--------------|
| Ingredient                  | % w/w        |
| Taste-masked drug*          | 0.5–25       |
| PanExcea MC200G             | 40–60        |
| Diluents (Optional)         | 10–30        |
| Disintegrants               | 5–20         |
| Other excipients (optional) | 0–10         |
| Lubricant                   | 0.5–3.0      |

* Taste-masking of an API by any suitable method.

| TABLE 2 High Dose Drug Orally Disintegrating Tablets |
|-----------------------------|--------------|
| Ingredient                  | % w/w        |
| Taste-masked drug*          | 20–50        |
| PanExcea MC200G             | 20–60        |
| Diluents (Optional)         | 5–20         |
| Disintegrants               | 5–20         |
| Other excipients (optional) | 0–10         |
| Lubricant                   | 0.5–3.0      |

* Taste-masking of an API by any suitable method.

Excipients can be selected from any of the following:

Diluents: Microcrystalline Cellulose, Lactose, Xylitol, Mannitol, Starch, Dicalcium Phosphate

Disintegrants: Sodium Starch Glycolate, Croscarmellose Sodium, Crospovidone, Starch 1500

Other Excipients: Sweeteners, Flavors, Colors, Stabilizers, etc.

Lubricant: Magnesium Stearate, Talc, Colloidal Silicon Dioxide, Sodium Stearyl Fumarate
A general process for the preparation of a representative ODT formulation is indicated below:

**Desired Tablet Properties:**
- Hardness: 20–60 N (Determined by the desired tablet weight and tablet punch dimensions)
- Disintegration Time: less than 20 seconds
- Friability: less than 1% w/w of tablet weight

1. Coarse screen the API or taste-masked API, PanExcea™ MC200G performance excipient and other ingredients
2. Active or taste-masked active
3. MC200G, diluents disintegrants and other excipients
4. Load and blend in a suitable blender/mixer/mill
5. Add lubricant, glidant, flavors and antiadherant and mix for 2–5 minutes
6. Compress the blend into tablets

About Avantor™ Performance Materials
Avantor Performance Materials manufactures and markets high-performance chemistries and materials around the world under several respected brand names, including the J.T.Baker®, Macron Fine Chemicals™, Rankem™, Diagnova™, BeneSphera™, and POCH™ brands.

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