APPLICATION NOTE

Bulk Drug Refining and Evaluation of Physical Properties

Particle Size Distribution and SEM Observation of Ethenzamide

Overview

In the manufacture of pharmaceuticals, bulk refining of the drug and the control of its physical properties (shape, etc.) are important factors in improving the tablet properties (tensile strength, solubility and consolidation characteristic). Here, we discuss the optimum conditions for jet milling during the manufacture of drug products from ethenzamide (crystalline bulk drug) based on data from particle size distribution measurement and morphological observation under a scanning electron microscope (SEM).

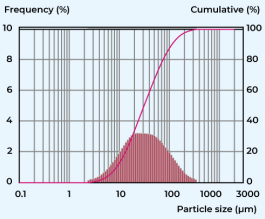
Jet Mill Performance Test

■ **Bulk drug**

• Electron microscopy

Magnification: x 2,000

• Particle size measurement



Instrument:
Microtrac MRB MT3000EXII

Measurement principle:
Laser diffraction / Light scattering

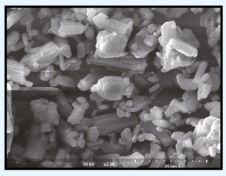
Measurement range:
0.02 - 2,000 μm

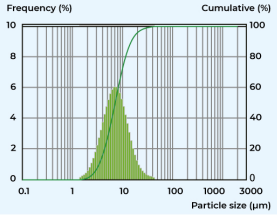
Measurement conditions:
Wet (Isopar G dispersion)

Loading

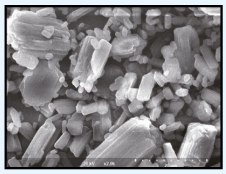
JET MILL

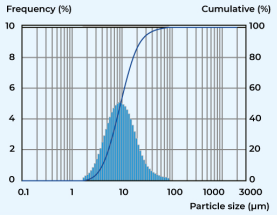
■ **Condition 1**
Air flow rate: 46 m³/ hr
Loading rate: 25 g / min



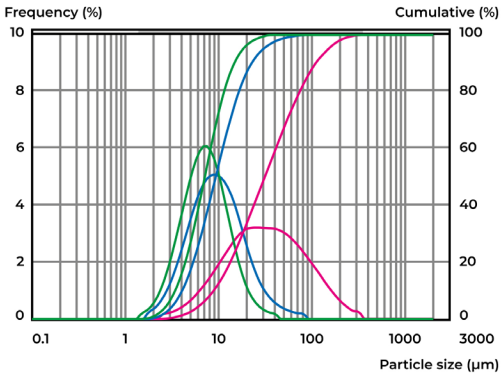


■ **Condition 2**
Air flow rate: 46 m³/ hr
Loading rate: 100 g / min





Evaluation of Jet Mill Performance (Particle Size Distribution)



: Bulk drug

: Jet mill crushing
Air flow rate: 46 m³ / hr
Loading rate: 100 g / min

: Jet mill crushing
Air flow rate: 46 m³ / hr
Loading rate: 25 g / min

Discussion

1. It was possible to observe the process during which the form of ethenzamide (an organic compound of high elasticity) became increasingly more roundish by jet milling.

2. It was confirmed that when the air supply to the jet mill was constant (46 m^3/hr), better refining was possible at a loading rate of 25 g/min rather than at 100 g/min.

Data source : Powrex Corporation & Iwaki Seiyaku Co., Ltd.

For further information please contact us at:

www.microtrac.com

