



## Weighing control in a GMP environment

**Dispensing material accurately and efficiently allows for complete confidence in the manufacturing process this is why Jewim Pharma approached METTLER TOLEDO to help them find a solution. Jewim Pharmaceutical Inc. is a medical conglomerate, with its headquarters located at Jewim Plaza, Beijing. Currently Jewim has over 1000 employees and growing.**

Jewim manufactures a number of different pharma products including aerosols, micro-powder (capsules), tablets (including double-layer tablets, special-shaped tablets), hard capsules, granules (dry suspensions), powders, oral solutions (including inhalation solutions), liquids for external use, creams (ointments) and multi-functional chemical pharmaceutical raw materials.

Jewim has state of the art production lines both home and abroad that were assembled and built according to GMP standards. Each year it can produce 5 billion tablets, 1 billion capsules, 400 tons of granules, 30 million tubes of aerosol (sprays), 10 million tubes of oral solutions (including spraying inhalation), 5 million tubes of creams (ointments), 2 million bottles of liquids for external use and 500 tons of Chinese herb processing.

The factories operate with a quality-guarantee system that meets the requirements of US GMP, European Union GMP and PICS.

In 2003, Jewim was awarded a National Chinese GMP Certificate and it has successfully passed a number of on-the-spot inspections. Besides the domestic market, their products are also exported to America, Africa, Asia and other regions.

Jewim were looking for a solution to aid in the manufacture of the intermediate API for their production of pharmaceutical aerosols designed for oral ingestion. The manufacturing process required the blending of raw materials prior to manufacture. To manufacture APIs with confidence the solution needed to be extremely accurate and fast as the weighing ter-

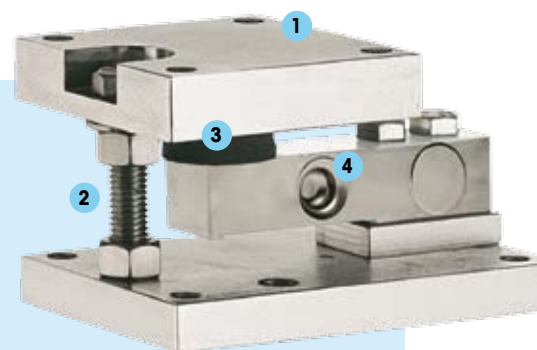
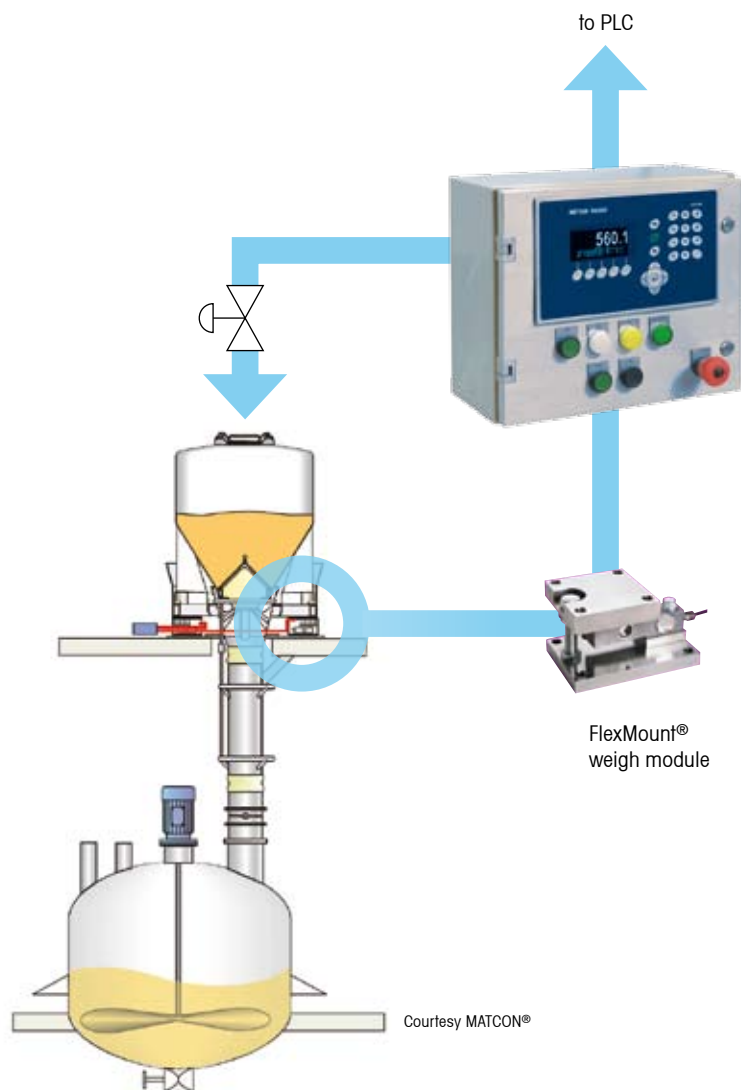


dence the solution needed to be extremely accurate and fast as the weighing terminal would automatically control the charge of the ingredient.

## Complete formulation control

The solution devised by METTLER TOLEDO combined the accurate FlexMount® weigh module with the quick process control of the IND560. The IND560 was upgraded with a FILL software package turning the terminal into an advanced filling controller capable of automatic filling.

The raw materials are loaded into hoppers mounted onto FlexMount® weigh modules. Once the hopper is in place the operator can instruct the IND560 to weigh the desired amount and the terminal will automatically fill the hopper. The high speed processing of the IND560 connected to an electromagnetic valve combined with the accurate FlexMount® weigh module results in a very precise and reliable batching system.



### FlexMount® weigh modules

- 1** The floating, semi-floating or fixed top plate design provides system checking while allowing the structure to expand and contract.
- 2** The anti-lift/jacking bolt prevents vessels from tipping over, and provides a convenient method of lifting empty vessels for maintenance and service activities.
- 3** The stainless steel load pin makes point contact with the load cell for optimum accuracy.
- 4** The hermetically sealed load cell offers excellent performance and durability.

- Anti-lift device restrains tank from tipping
- Carbon steel and stainless steel design
- Accuracy: 3000e OIML & NTEP 5000e class IIIIM
- FlexMount® capacity range: 113 to 4400 kg (250 to 10000 lb)
- Hazardous Area: ATEX and FM approvals Zone 1/21 or Division 1

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# Automated solutions for process control and final product checking



## Save money with advanced control

Valves and feeders can be directly controlled from the IND560fill, eliminating the need for a costly PLC. Discrete inputs provide sequence control from local or remote locations. The SmartTrac™ graphical display provides a visual representation of process status.

## Improve process quality and personnel efficiency

The Learn Mode and Automatic Spill Adjustment capabilities provide a means

of continuously refining the accuracy of the weighing process. Operators can be freed up for additional tasks by using the Automatic Sequence Control, or the operator's input can be focused on critical points in the process by selecting the Semi-Automatic Mode.

## Filling and dispensing flexibility

The IND560fill can be used with simple single material or more advanced multiple material applications. The entire contents

can also be dispensed or dosed in a precise, controlled manner into single or multiple containers for the weigh-out cycle. In addition, the operator may program the controls to repeat the process a set number of times.

### IND560fill: Features and Benefits

- Weigh from milligrams to tons
- Control manual, semi-automatic and automatic processes
- Comply with industry regulations and global approvals
- Connect your system to PLCs, LANs, WANs, and the Internet
- Certified for Zone 1 and 21

## Final product checkweighing

Jewim Pharma also check the weight of their finished products using a solution provided by METTLER TOLEDO, the Garvens S2 checkweigher.

## The Garvens XS2 Pharma checkweighers the successor model to the S2 Pharma checkweigher.

Specially developed for the pharmaceutical environment – and the result of ongoing development in dynamic weighing technology – the Garvens XS2 pharma checkweigher features an easy-to-use 15" touchscreen, on-screen operator prompts, digital load cell for improved accuracy and throughput, and has the advantage of a modular design which allows specific solutions to be supplied from standard software and hardware modules.



## Innovative solution for weighing Active Pharmaceutical Ingredients

**Founded in 1997, ScinoPharm Taiwan is a leading active pharmaceutical ingredients (APIs) supplier to the global pharmaceutical and biotechnology industry. It provides a full range of API services from process development, production of early phase clinical trial material to large-scale manufacturing for commercial launches.**



Courtesy ScinoPharm



台湾神隆股份有限公司  
ScinoPharm Taiwan, Ltd.

Located within the Southern Taiwan science park in Tainan, ScinoPharm operates a state-of-the-art cGMP certified multi-purpose manufacturing facility which has passed inspections by various international regulatory agencies including the United States FDA, Australian TGA, Japanese PMDA, and one of the EU countries (Hungarian NIP).

The company's facilities, specifically designed to manufacture cytotoxic and high

potent compounds, can readily handle oncology and hormonal products, as well as most other APIs made of small molecules, peptides and nucleic acids.

Managed by a team of highly proficient industry professionals, this fast-rising company is already a name to reckon with in the API industry. At present, ScinoPharm serves more than 190 customers throughout the world, including most of the largest brand and generic drug companies.

As it continues to grow its global presence, the need to provide its customers with the highest level of quality have led it to introduce advanced technology not just in production but in weighing too. The man-

ufacturing process of pharmaceutical ingredients requires the accurate weighing of raw materials to achieve and maintain the necessary identity, quality and purity. Hence when ScinoPharm needed an accurate weighing solution for the manufacturing of active ingredients, they contacted METTLER TOLEDO.

### The innovative solution

Thanks to an optimal solution introduced by METTLER TOLEDO, the weighing operations at ScinoPharm facilitated the company's quality management. METTLER TOLEDO's solution combines a terminal with an ultra-low profile scale thus satisfying the customers demands.



Low profile scales such as the 2888 Deckmate® (available in North America, UK and Taiwan) and the PUA579 (available globally) provide the ideal solution where space is at a premium. Both are designed for use in hazardous environments and the low profile design allows for easy loading.

These low profile scales can then be combined with a terminal such as the PUMA®/ID3sTx which is designed to be used in hazardous areas.

**ID3sTx**



ATEX Cat 3 (G/D) Zone 2, 22; ATEX Cat 2 (G/D) Zone 1, 21  
 FM: Class I,II,III; Div1; Groups A-G/T4A



Low profile scale  
**2888 Deckmate®**



Low profile scale **PUA579**

**Simple, flexible, durable: ID3sTx**

- Easy to install and operate
- Low power consumption for a long battery life up to 380h
- Rugged stainless steel construction, IP65
- Immunity to electrical interferences due to fiber optic data communication
- Certified for Zone 1 and 21

## CarePac: Professional Weight Set to Ensure Balance Accuracy



**Routine balance testing is the most economical way to ensure accurate results every time. CarePacs are designed to respond to ever increasing time pressures by offering fast and convenient balance testing.**



Hans Joerg Burkhard, Weight Business Manager at METTLER TOLEDO

We asked Hans Joerg Burkhard, Weight Business Manager at METTLER TOLEDO, to tell us more about the importance of routine testing and to explain the advantages of the recently introduced CarePacs.

■ Hans Joerg, could you please give our readers some insight into routine testing and its importance in ensuring accurate weighing results?

Balances play a key role at the very beginning of daily laboratory analytical testing. The accuracy and reliability of weighing results with even the smallest quantities have a direct impact on final test results. To ensure that weighing results are within process tolerances, the balance needs to be regularly tested with externally calibrated weights. This is often a challenge as time constraints and limited resources do not allow for in-depth balance testing. In this respect, CarePacs are greatly beneficial as correct weighing results and adherence to process tolerances can be achieved through regular routine testing with certified weights.

■ How do you perform a typical routine test and how often does it need to be done?

Routine testing is performed using calibrated and certified weights to ensure compliance with national or international

standards. Typically, tests are executed from the upper to lower weighing range, i.e. at or close to maximum load and at approximately 5% of the weighing range. Testing frequency is dependent on many factors such as process tolerances, associated process risks and laboratory practices.

■ How do CarePacs support routine tests performed by customers?

The new approach with CarePacs is that they only contain two calibrated and certified test weights, which is in sharp contrast to the traditional approach where customers were forced to buy an entire weight set with up to 20 weights. Test weights in CarePacs are recommended by METTLER TOLEDO and nominal values and weight classes are adapted to the technical characteristics of each specific balance model. The initial cost of CarePacs is a fraction of that compared to conventional weight sets. Another great advantage of CarePacs is that re-calibration costs are very low as only two weights need to be calibrated. Ergonomic tweezers and weight forks, clean room



Hans Joerg Burkhard is Weight Business Manager at METTLER TOLEDO headquarters in Switzerland. During the design and construction phase of CarePacs, he worked in close cooperation with customers from various industries.

approved gloves and a cleaning cloth for correct weight handling come as standard with each CarePac. Manufacturer recommended SOPs (Standard Operating Procedures) provide clear guidance and ensure consistent processes of routine balance tests.

■ Hans Joerg, thank you for sharing this information with us

If you have questions about METTLER TOLEDO's CarePacs contact Hans Joerg Burkhard at:

▶ [hans.joerg.burkhard@mt.com](mailto:hans.joerg.burkhard@mt.com)  
▶ [www.mt.com/carepac](http://www.mt.com/carepac)



Three sizes of CarePacs allow routine testing of balances up to 8 kg weighing capacity.



Professional accessories such as ergonomic tweezers and weight forks, clean-room approved gloves and cleaning cloths match highest requirements of all industries.

# A wide range of solutions to improve processes

1. Process terminals, IND780
2. Weigh modules, SW515 PINMOUNT
3. Vehicle scales, Powercell®
4. Stainless steel drive through scale, PUA579



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Learn more about all of our solutions for the Fine Chemical industry at our website. Here you can find information on a wide range of topics to improve your process,

case studies, applications stories, plus all of the product information you need to make an informed decision.

► [www.mt.com](http://www.mt.com)

Brochures/Catalogs:

1. Brochure: Process weighing
2. Hazardous Area Brochure
3. Weighing Components Catalog 2008
4. Industrial Weighing Catalog 2008



### USA

Mettler-Toledo, Inc.  
1900 Polaris Parkway  
Columbus, OH, 43240  
Tel. (1) 800 523 5123

### Canada

Mettler-Toledo, Inc.  
6419 Northam Drive  
Mississauga, Ontario, L4V 1J2  
Tel. (1) 800 523 5123

### Mettler-Toledo AG

Sales International  
CH-8606 Greifensee  
Switzerland  
Tel. +41 44 944 22 11

Your METTLER TOLEDO contact:

[www.mt.com/ind-api](http://www.mt.com/ind-api)

For more information