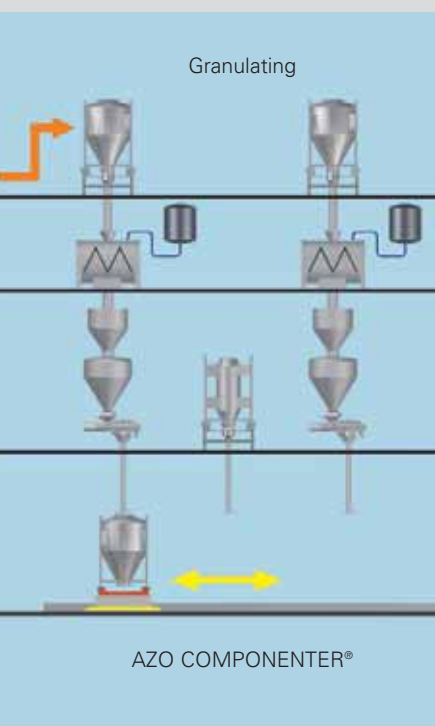


Highly flexible and contamination-free: Automated container systems for the manufacture of tablets

THE SOLUTION



KONIMEX

 **AZO**[®]
Right to the point.



Automated container systems for the manufacture of tablets in the pharmaceutical and food industries

»For Konimex as a global company, with a mission statement that emphasises health throughout all of our corporate dealings, the following points were decisive for us in our selection of supplier for the bulk material engineering in the new plant: The plant has to meet the most exacting standards in terms of hygiene and precision so that we can guarantee an exceptional quality of product at all times. As a global player, AZO is very familiar with international standards and this corresponds perfectly with the corporate philosophy of Konimex. The superior concept in combining an AZO COMPONENTER® and a container mixer excited the customer even at the planning stage.«

Our customer **KONIMEX**

From drugs to sweets, snack foods to natural remedies. The product range of Konimex, our customer in Indonesia, is shaped by the philosophy that a happy life means above all a healthy life. The pharmaceutical division therefore also represents the flagship of the Konimex Group. In addition to

prescription medications and nutritional supplements, such as vitamin products, the company has been increasingly manufacturing natural remedies in the recent past. The dosage forms range from tablets, capsules and effervescent tablets to syrups and ointments.





The objectives of the investment

- Manufacture of drugs and nutritional supplements with low staffing levels
- Increasing efficiency and capacity
- Closed system to eliminate contamination and protect the product from humidity
- Reliable batch tracking and tracing
- Safe product and user protection

The task

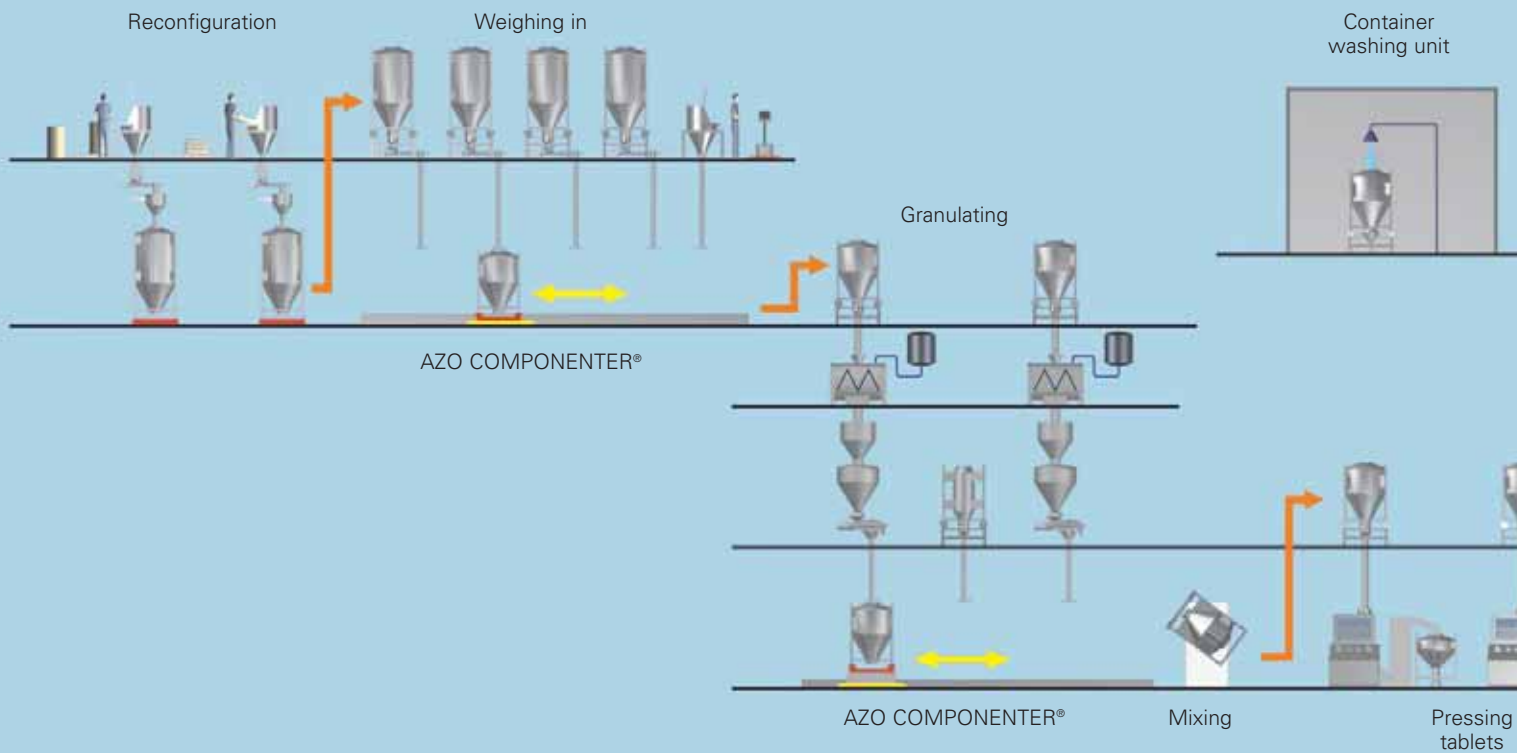
The new plant was integrated into existing buildings. The issue was to implement two different production lines. Headache tablets in blister packs would be manufactured on one line in the pharmaceutical area. On the second line, energy drinks and nutritional supplements, in the

form of effervescent tablets, would be manufactured in a separate building for the food division. What was required were the very latest container systems, which would set new benchmarks in terms of batch traceability, improved capacity and flexibility. The entire manufacturing process has

to be transparent, comprehensively documented and exceptionally flexible. The most exacting standards are required in terms of cleanliness and hygiene and the entire plant design therefore complies with pharmaceutical standards. The issue of quality assurance is also very important.



Highly flexible and contamination-free: Automated container systems provide clear advantages for the manufacturing of tablets and effervescent tablets



The AZO solution for the pharmaceutical division: Automated container system for the manufacture of headache tablets

The AZO solution in detail

Transferring sacks and drums into internal containers

There are several stations with feeding hoppers available in this area. Drums and sacks containing carrier substances and active agents are transferred practically dust-free through these hoppers into the closed system. Barcode readers and touch screen terminals with on-site process visualisation ensure that only the

correct raw materials can be fed in. The lid of the feeding hopper can only be opened when the operator has identified the container. As soon as the lid is open, an aspirator starts up immediately, which ensures that no dust is discharged outwardly when the product is fed in. As these are partly very hygroscopic products,

a lump breaker or sieve mill can be fitted downstream of the feed process if required, to convert the raw material to the grain size required. After this or directly after direct metering by a dosing screw, the raw material containers are then filled, the so-called BATCH-TAINERS®, which stand on floor scales. The weight of the filled

charge is recorded and the data is saved on a transponder, so that it is possible to identify at any time, which quantity of which product is in the BATCHTAINER®. Following the transfer process, these BATCHTAINERS® are placed in line on an AZO COMPONENTER® unit on docking stations.



Feeding of sacks with barcode logging



Filling sacks into the closed system



Feeding products out of drums into the closed system



Packing

The tasks at a glance

- Reconfiguration of the active and carrier ingredients supplied in sacks and drums into BATCHTAINERS®
- Breaking down of agglomerates using a lump breaker and producing a defined grain size with a sieve mill
- Automatic weighing of carrier substances by an AZO COMPONENTER®
- Gram-exact manual weighing of active ingredients with a ManDos weighing station
- Batch granulation
- Weighing the granulated product in a second AZO COMPONENTER®
- Mixing the batches in a container mixer
- Feeding the tablet containers and tablet presses
- Feeding the blister machines
- Automatic cleaning of the containers when changing the recipe
- Controlling and monitoring the entire production process via a central process management system and decentralised operation terminals

Gram-exact weighing, granulating, and container mixing process

ManDos – Gram-exact manual weighing of active ingredients

A ManDos weighing system is provided in this highly sensitive area. It guides and monitors the operator during the manual weighing of active ingredients. The operator begins by identifying the raw material to be weighed

and then manually weighs the required quantity into a bag situated on a table scale. The bag is then sealed and provided with a barcode, which is generated during the weighing process. The now clearly marked and coded

active ingredients are transported to a special feeding hopper within the AZO COMPONENTER® line and can there be fed dust-free

into the automated weighing and metering process.



ManDos weighing system for weighing active ingredients



Barcode logging of the precisely weighed active ingredients



Automated collection and weighing of the components by an AZO COMPONENTER®

Automatic weighing of carrier substances and active ingredients

AZO COMPONENTER®

An AZO COMPONENTER® system is used for automatic weighing. The BATCHTAINERS® containing the carrier substances stand in a line on docking stations, which are fitted with dosing screws. As soon as the BATCHTAINER® has been placed on a docking

station and the outlet flap is opened, the product is automatically metered via a dosing screw into another BATCHTAINER® on the level below and simultaneously weighed (according to the recipe). This batch container is guided to the individual metering

points by the driving unit that is supported on one side according to the recipe.

Granulating

The batches, which have been weighed into the BATCHTAINER® using the AZO COMPONENTER®, are then granulated. This can be wet or dry granulation depending on the further processing of the product. The granulated products are then weighed according to the recipe.



BATCHTAINERS® above the AZO COMPONENTER®



In the background: Granulation unit



BATCHTAINER® on mobile floor scale – AZO COMPONENTER® for weighing the granulated products



Automated transfer from the BATCHTAINER® to the container mixer

Weighing the granulated products

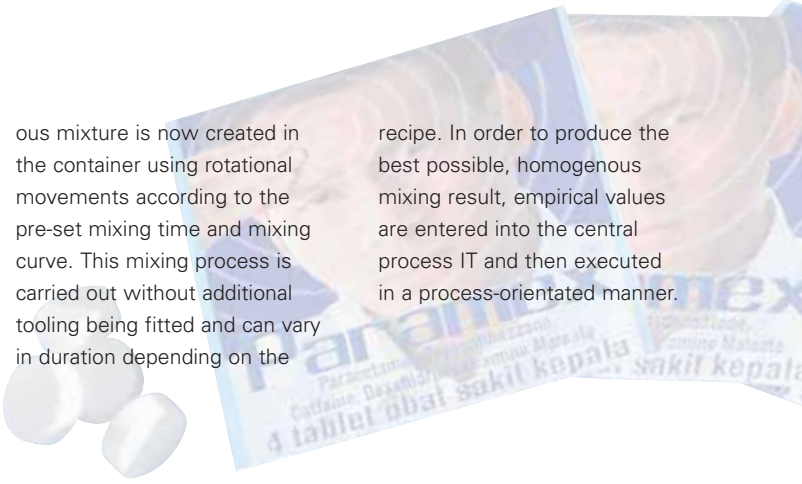
A further AZO COMPONENTER® line with a mobile, single-side-guided weighing scale is used for this purpose. The container passes under the metering points. The granulated product is metered and weighed exactly according to the recipe. Once all the components are in the BATCHTAINER®, this is then transported on the mobile floor scale to the container mixer.

Container mixing process

The container is transferred from the AZO COMPONENTER® directly into the container mixer and fixed there with hydraulically actuated pincers. The cover lock clamps the automatically placed container cover, making the container dust-proof during mixing. A homogene-

ous mixture is now created in the container using rotational movements according to the pre-set mixing time and mixing curve. This mixing process is carried out without additional tooling being fitted and can vary in duration depending on the

recipe. In order to produce the best possible, homogenous mixing result, empirical values are entered into the central process IT and then executed in a process-orientated manner.



Production of a homogeneous mixture with the help of a container mixer



BATCHTAINER® with finished mixed product for feeding the tablet presses on the below level

Packaging

Feeding of tablet presses and tablet containers

The BATCHTAINERS® are transported to pick-up stations following the mixing process and stacked there by fork-lift or lifting truck and fixed in position. Depending on the behaviour of the bulk material, it is also possible to assist the discharge process using vibration. The tablet presses are located a level below the pick-up stations. It is necessary to ensure that the product does not land on the

tablet press when free falling, in order to prevent demixing. An intelligent solution ensures that the mixture falls very continuously and slowly. This ensures that consistently homogenous mixtures can be achieved in the successive tablet pressing process. After the finished tablets have fallen out of the tablet press, they are lifted up by a special transport system and filled into the tablet container. This is equipped with a docking fitting.

Feeding of blister machines

The tablet containers are fitted with cascades on the inside and have an outlet with a manual locking cone. After placing the tablet containers on the filling machines, the tablets are transferred carefully and without breakage to the blister machines via a tablet lift. The extensive experience of AZO in the handling of tablets is evident in this area.

Automated container washing unit

Using the transponder, with which every BATCHTAINER® is fitted, it is possible to identify precisely when a container has to be sent for cleaning into the automated container washing unit. This is always the case when a new recipe is processed. The containers are cleaned in specified intervals during longer production campaigns of the same recipe.



Tablet containers on pick-up station for feeding packing machines



Automated container washing unit



Central control panel with process management and visualisation system

Process management and control

Central process management and visualisation system

The monitoring and control of the entire system is done from a central control panel with a process management and visualisation system. Intelligent local touch screen terminals help the operator to call up information and make process-relevant inputs. The process management and visualisation system documents the entire value-added process

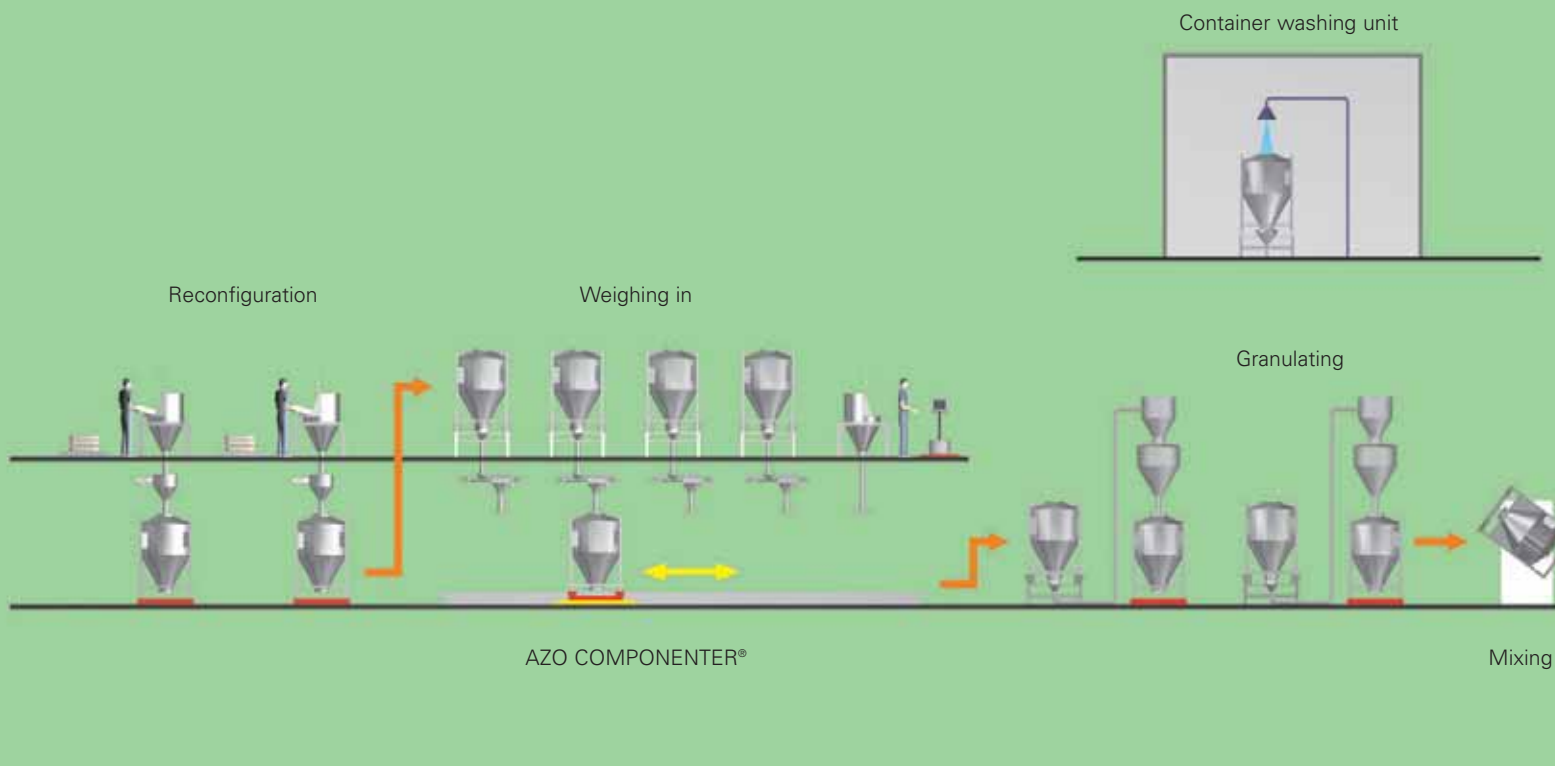
and ensures maximum transparency. Using barcode identification, reliable product tracing is guaranteed from the feeding of raw materials right through to the finished product. By equipping containers with transponder systems, the operator knows exactly at any point in the manufacturing process which container is positioned where, what it contains and when the next cleaning cycle must take place. This ensures a high degree

of batch tracking and tracing, as well as production reliability. A further reliability factor is the direct data exchange with the HOST system via a database interface. This guarantees the reliable identification of components with real-time checking and authorisation for production. In addition, the ancillary conditions can be continuously called up, such as sell-by date, product assignment and batch status. The transparency of material

and data flows, as well as the constant availability of meaningful real-time values, enables decisions to be made quickly and the operator to react appropriately in critical situations.



Operator control terminal on-site



Automated container system for the manufacture of energy drinks, nutritional supplements and vitamin products

The AZO solution in detail

Supply and cleaning of the containers

The raw materials are supplied in the form of sacks and drums. Before these enter the actual manufacturing process, they are placed on an inclined conveying belt and pass continuously through a closed cleaning unit. There the sacks and drums are

cleaned by blowing and suction and leave the cleaning plant in a fully automated manner in a clean, dust-free state.

Transferring of sacks and drums into internal BATCHTAINER®

Feeding hopper stations are used to ensure the sacks and drums are emptied in a low-dust environment. As soon as the lid of the feeding hopper has been opened, an aspirator starts up which creates a gentle flow of air inwards.

Airborne particles are thus sucked away from the operator towards a central aspiration system. As both drums and sacks are fed in successively, an additional module makes the handling of drums much easier.



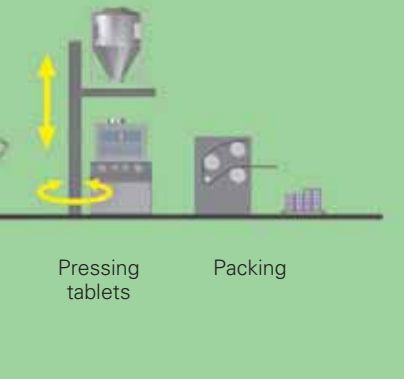
Feeding hopper for feeding sacks and drums into the closed system



Feeding hopper with special equipment for feeding drums

The tasks at a glance

- Supplying and cleaning of sacks and drums
- Transferring of sacks and drums into BATCHTAINERS®
- Breaking down of agglomerates using a lump breaker and producing a defined grain size with a sieve mill
- Automatic weighing by the AZO COMPONENTER® with control-screening
- Manual weighing of raw materials to within a gram using a ManDos weighing station
- Batch granulation
- Mixing of batches in a container mixer before and after granulating
- Feeding of product to tablet presses
- Automatic cleaning of the containers when changing the recipe station
- Controlling and monitoring of the entire production process via a central process management system and decentralised operating terminals



Lump breaker/sieve mill – Feeding of BATCHTAINERS®

Once the products have been fed from the drums and sacks into the feeding hopper, the raw materials are transported to a combined lump breaker and sieve mill. As these are partly very hygroscopic products with a tendency to form agglomerates, a lump breaker

breaks down the agglomerates and the downstream sieve mill converts the raw materials into a defined grain size. Thereafter, the products are fed into BATCHTAINERS® via a discharge pipe and docking unit. These are standing on a floor scale. This

records the quantity closed in and stores this data on the BATCHTAINER® transponder.



Pre-dispensing feeding hopper with lump breaker



Lifting column with conical mill for feeding a BATCHTAINER®



AZO COMPONENTER® for automated collection and weighing of the components

Precise weighing processes and granulation

Automated weighing in the AZO COMPONENTER®

The automatic weighing process consists of BATCHTAINERS® at the top level and a pick-up station for micro quantities or active agents, which are pre-weighed by a ManDos workstation and are fed to the automated weighing process via a feeding hopper. Metering takes place in the lower level via a cyclone

screener into a BATCHTAINER® placed on a mobile scale. The detailed process is as follows: The BATCHTAINERS®, which were filled at the reconfiguration station, are transported to the top level by a lift and placed on the container pick-up stations by a lifting mechanism. Should additional vibration be required, the BATCHTAINER® has to be fixed in position by means of pneumatically operated clamps. The transponder and

various barcode systems ensure that no BATCHTAINER® is placed on the incorrect docking station. Docking takes place via the patented docking collar, thus ensuring dust-free bulk material transfer into the subsequent system. The BATCHTAINER® remains fixed on the container pick-up station for as long as the raw materials are part of the particular recipe. When the container changes, the closing

flap is simply closed and the fixing is released if necessary, then the BATCHTAINER® can be transported away.



Pick-up stations for BATCHTAINER®



Screener with docking for metering into BATCHTAINERS®



Gram-exact weighing, labelling and collection of active ingredients

ManDos – Gram-exact manual weighing of active ingredients

A ManDos system is available for weighing active ingredients. The operator can see on the terminal which quantity of active ingredient he should be weighing. Prior to the manual weighing, the operator identifies the correct raw material with the barcode scanner. Once the active ingredient has been weighed exactly to the gram, the bag is sealed and given a label generated by a barcode printer.

The bags with the different active ingredients are then dropped into a barcode-secured feeding hopper to ensure that the correct active ingredients are in the feeding hopper. The fully automated weighing process can now start in the BATCHAINER®. This stands on a mobile weighing scale, which passes below the different metering points. The quantity stipulated in the recipe is then metered exactly and weighed. A unique feature of this system is the fact that all

the raw materials used are control-screened. The screener type DA follows the container pick-up station and ensures that no impurities find their way into the subsequent process. A further advantage of the cyclone screener is the fact that it produces a very even metering flow, which ensures a high degree of accuracy when weighing.

Granulating

Separate cabins are available for the granulation process. The weighed batches are then pneumatically conveyed to a granulation process. The finished granulate is then filled into a BATCHAINER®. Yield weighing is accomplished by means of a mobile floor scale and the result is then stored on the transponder. The content of the container is documented and is identifiable at any time for the subsequent process.



BATCHAINER® on mobile scale



Filling the BATCHAINER® after the granulating process



Container mixer

Container mixing process and packaging

Mixing the batches in a container mixer

The BATCHTAINER®, which is filled with granulate and possibly further additives, is transported directly to a separate mixing room by lifting equipment and placed into the holder of the container mixer. There it is fixed by means of a hydraulically operated mechanism. The speeds and mixing times can be adjusted as required, so that high quality

mixtures can be achieved with different properties of the components to be mixed. The circular design of the BATCHTAINERS® guarantees a high level of stability and is thus ideal for container mixing processes. No additional static mixing aids or tools whatsoever are required in the container.

Product feed to tablet presses

After mixing, the BATCHTAINER® is transported to a lifting and swivelling column by a fork-lift or lift truck. Here it is fixed in the holder, raised, swivelled over the tablet press and docked dust-proof. An outlet flap on the outlet opens to empty the finished mixture from the BATCHTAINER®. The homogeneously mixed batch thus flows into the subsequent tableting process.

Automated container washing unit

After emptying, the controller checks whether there is to be a change of recipe, otherwise the BATCHTAINER® can be re-used without the need for intermediate cleaning. Often the container is cleaned in the automated washing unit after every production run for safety reasons.



Lifting column for feeding the tablet press from BATCHTAINERS®

Further functions of the Kastor process management system:

- Identifying raw materials at delivery, transferring to and from stock, filling, transferring, identifying (reading, writing, barcode-compatible (39, 128, EAN), RFID), PDA-, WLAN-compatible
- Information points displaying production status (order progress), fault alerts, actions required, truck unloading and loading processes etc.
- Transfer to downstream packing machines
- Filling and emptying containers (return containers, barcode identification/labelling (39, 128, EAN), transponder, RFID)
- Multi-state production processes are possible with tracing of the raw material use, overlapping of orders and batches
- Can be combined with manual weighing
- Calculation of active ingredients, water content, production factors
- Optional handling of weighing tolerances according to the requirements of the order recipe, component requirements or weighing parameters / weighing range
- Cleaning supervision

Process management and control

Intelligent IT process

Fully automated container systems require very exact control and supervision. A central control panel is provided for this purpose, with which the complete process can be controlled and managed via the intelligent process management and visualisation system. In addition, operation terminals are provided on-site in the individual processing and process stages,

with which the operator can carry out operating functions by means of a touch screen.

Kastor – Batch-orientated process management system for automated feeding systems

The combination of the innovative Kastor process management system with a standard tools-based visualisation process provides a central process management and visualisation system that facilitates a wide range of workflow controls. Moreover, this central system provides consistent documentation of the production sequences (Active Factory), such as batch

reports and yield balances, as well as long-term archiving of the data collected. It guarantees individually configurable access protection, system safety and validation capacity in compliance with GAMP 4 and FDA provisions. The process management system also has a master data administration system, based on the provisions of the S88 guidelines. Kastor is also connected to the parent customer system for transferring recipe and order data.



Process management and visualisation system



Operation terminal on-site



Conclusion:

New benchmarks have been set, in terms of batch traceability, improved capacity and flexibility in fully automated container handling systems with the implementation of this innovative concept, the combination of an AZO COMPONENTER® and a container mixer. Currently many our customers producing effervescent tablets are very happily and satisfactorily using AZO systems.

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Right to the point.