

AUTONOMOUS PREPARATION SYSTEMS

This makes the production of granulation liquids, colouring solutions and sterile preparations a no-brainer

Dear Customer,

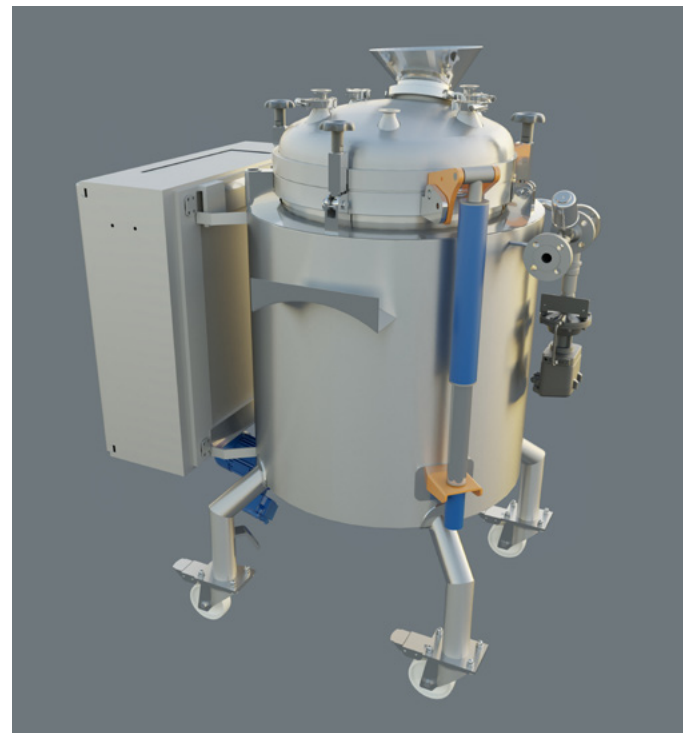
We are pleased to present our innovative, autonomous system for the production of granulation liquids, colouring solutions and sterile preparations. With its own control system and recipe management software that can be validated, the system enables both automated and semi-automated preparations.

Precise dosing of the components is carried out by means of pharma-compliant flow measurement systems or prefabricated barcode registered containers. The system has an integrated control unit that facilitates the creation of batch records and the tracking of partial batches.

Featuring a working volume of 33 – 180 l and an electropolished, dead space-free design, the system offers a GMP-compliant magnetic stirrer. Operation is carried out via a visualised user interface with touch screen from 12" to 17". It meets the requirements of GAMP 5, 21 CFR Part 11 and is CIP/SIP capable. In addition, the tank can communicate with downstream production units.

Optional equipment includes heating and cooling jackets, electrical trace heating, pressure vessel design, ATEX design, high containment design and barcode scanner for pre-weighed partial batches. The system can be operated via tablet and is also suitable for ATEX applications.

To ensure that the system always functions perfectly, we offer a remote diagnosis system that enables process support, remote maintenance and troubleshooting around the world and around the clock. PRUESS will only



have access to the plant after the hardware has been connected by authorised personnel of the customer.

A UPS power supply provides a controlled shutdown of the control system in the event of a power failure as well as log storage with all process-relevant parameters.

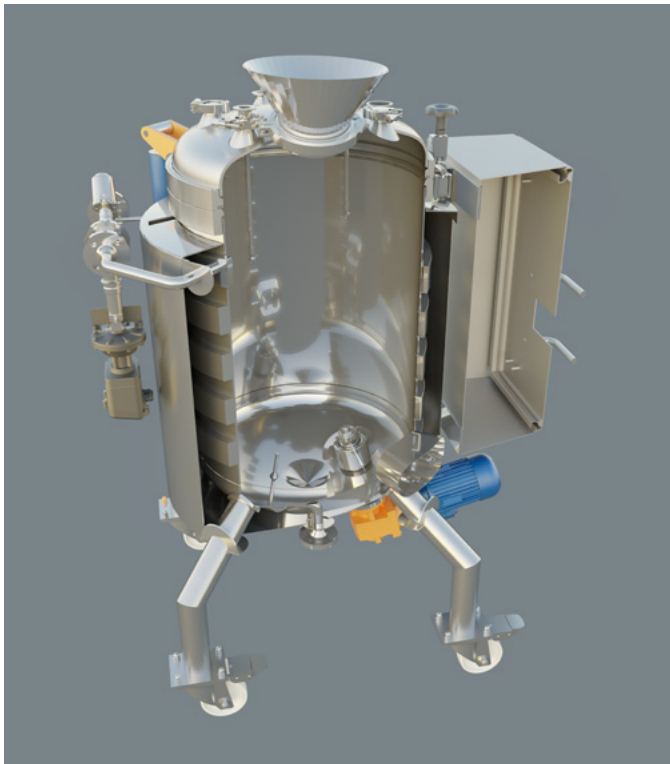
If you have any further questions or are interested in a presentation, please do not hesitate to contact us.

With kind regards
Your PRUESS GmbH team



PRUESS GmbH has developed an autonomous preparation and mixing system for the production of granulation liquids, colouring liquids and for a variety of sterile preparations. By using its own control unit, this system has a recipe management software that can be validated and used to produce automated as well as semi-automated preparations.

All sub-components can be precisely identified by scanner via prefabricated containers or can also be added by means of pharma-compliant flow measurement systems. Batch records can be generated by the control unit built into the system. The information important for tracking partial batches is recorded both at the actual place of production of the preparation and at the point of use.



Basic equipment

- Working volume 33–180 l with a nominal volume of 200 l
- GMP-compliant magnetic stirrer
- Dead space-free design
- Own control system with visualised user interface
- Recipe control for production processes
- Batch record
- Data transfer to the customer's PCS
- Communication with downstream production units such as high-shear mixers and coating systems
- CIP/SIP
- HMI as touch screen in 12–17"
- Meets the requirements of GAMP 5 and 21 CFR Part 11

Optional equipment

- Heating and cooling jacket in the cylindrical section with fully welded insulation
- Electrical trace heating
- Pressure vessel design
- ATEX version, inside zone 0, outside zone 1, 2, 21, 22
- High-containment design for the addition of solids via split butterfly valves
- Connection to customer measuring devices such as weighing systems, flow measurements, etc.
- Barcode scanner for pre-weighed partial batches
- Tablet operation also for ATEX applications
- Remote diagnosis system
- A software programme is installed on the PC for remote diagnosis and as a maintenance tool. This enables PRUESS to provide process support, remote maintenance or troubleshooting to the customer on demand, anywhere in the world and at any time. For security reasons, PRUESS only has access to the plant after an authorised employee of the customer has established the hardware connection.
- A UPS power supply enables a controlled shutdown of the preparation system in the event of a power failure.



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