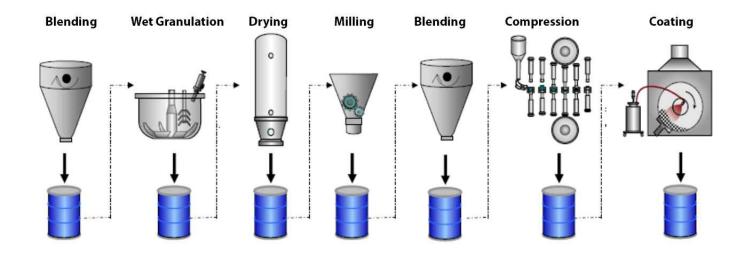




# **CHANGING**

THE WAY WE MAKE AND TAKE MEDICINES





### **CURRENT BATCH MANUFACTURING PROCESS -**

### **LOW EFFICIENCY, LOW QUALITY, HUGE BURDEN**

The batch manufacturing process, followed by the industry even today, requires sample collection and testing after each unit of operation to assure quality. The actual processing time runs into days and weeks. This results in low efficiency in terms of cost and time, inconsistencies in quality and sub-optimal yield, besides being a regulatory burden. Batch processing also requires large manufacturing spaces, increasing the footprint required for production.

#### IT'S TIME TO CHANGE

"Right now, manufacturing experts from the 1950s would easily recognize the pharmaceutical manufacturing processes of today. It is predicted that manufacturing will change in the next 25 years as current manufacturing practices are abandoned in favor of cleaner, flexible, more efficient continuous manufacturing"

Dr. Janet Woodcock M.D., Director, USFDA, Center for Drug Evaluation and Research

"The whole industry is discussing continuous manufacturing. The other issue related to mindset is that companies have to change the way they are doing Process R&D, and that takes effort"

Bernhardt Trout
Director of the Novartis-MIT Center for Continuous Manufacturing

"I don't know why it's not more widely used" as "this is the future."

Dr. Janet Woodcock M.D., Director, USFDA, Center for Drug Evaluation and Research



## STEERLIFE'S NOVEL BATCH TO CONTINUOUS (B2C) PROCESSES USING THE FRACTIONAL LOBE PROCESSOR

In STEERLife's continuous manufacturing processes, materials are charged and discharged simultaneously during the processes. This not only allows for better consistency, it hugely impacts speed, scale of production and efficiency, besides significantly reducing the manufacturing footprint required for production.

- Novel hot melt extrusion (B2C –E) can replace conventional hot melt extrusion
- Hot Melt Fragmentation\* (B2C-F) can replace spray drying and spray congealing
- Activated Granulation (B2C –G) can replace conventional wet, dry and melt granulation.
  - Melt Granulation
  - Moisture / Shear Activated Dry Granulation\*
  - Continuous wet Granulation\*



## PROCESSES DEVELOPED USING STEERLIFE'S PROPRIETARY TECHNOLOGIES

#### HAVE THE FOLLOWING FEATURES:

- Continuous process eliminating hot spots and dead zones
- Self cleaning (self wiping), no residues of earlier runs
- Economical development
- Ease of scalability (both linear and non-linear)
- Traceable (stratified continuous stream)
- Versatile (Easily adaptable to meet differentiated needs during process development)
- Quality by design (Well established risk and product quality)
- No metal dust contamination

#### TRANSFORMING MEDICINE INTAKE

#### **EFFERVESCENCE** (EVT)\*

Effervescent compositions offer unique advantages such as administration in solution form. They are particularly useful for people with gag reflex or swallowing difficulty. Effervescent compositions from conventional techniques suffer from low carbon dioxide (CO2) content, low porosity, longer disintegration times and have low mechanical strength. STEERLife's advanced processes help create effervescent compositions with increased porosity, rapid disintegration times and high mechanical strength while retaining a greater percentage of CO2 (from the input blend).

\*Patent Pending

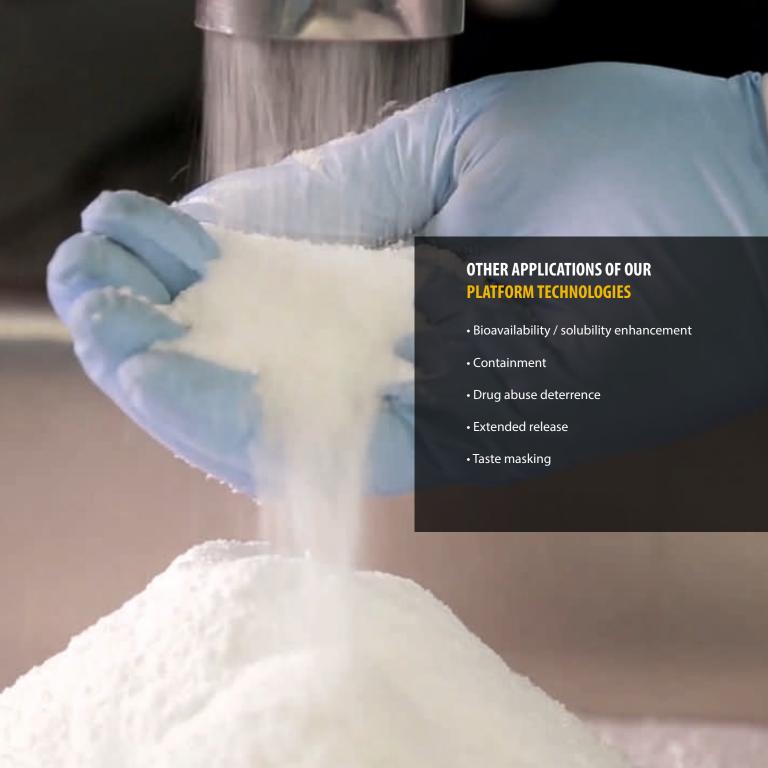
EFFERVESCENT TABLET FOR ORAL SOLUTION — useful for people who have problems swallowing. They are also helpful for improving the bio-availability of various classes of drugs. Converting the dosage forms into effervescent flavoured and sweetened oral solutions will enhance the acceptability of the medications.

#### RAPIDLY DISINTEGRATING TABLETS FOR ORAL SUSPENSION —

Rapidly disintegrating tablets (RDTs) are solid unit dosage forms with improved patient compliance. RDT's are especially helpful for children and older people who have problems in swallowing. These tablets disintegrate and disperse rapidly in a glass of water.

ORALLY DISINTEGRATING TABLETS (ODTs) — ODTs disintegrate with saliva and do not require any external source of liquid for consumption. They are especially useful for patients with dysphagia, or even children who are too young to swallow tablets or capsules.





#### ADVANCED PLATFORM TECHNOLOGIES FOR LAB AND PILOT SCALE NEEDS

At STEERLife, we design and develop advanced, customised, scalable platforms that can help manufacturers and research departments test and create formulations at the lab-level which can be easily scaled up for commercial needs. We also serve as a commissioned solutions provider to companies for lab and production-related technology requirements. Our platforms provide the necessary control, are scalable and can be customised to specific needs and requirements.

#### OMICRON 10 PHARMA — FOR PHARMACEUTICAL R&D LAB

#### B2C 12 — FOR PHARMACEUTICAL R&D LAB AND PILOT PRODUCTION



The above equipment is an example of the Omicron platform customised for specific requirements



The above equipment is an example of the B2C 12 platform customised for specific requirements

#### **CUSTOMISED SOLUTIONS FOR COMMERCIAL NEEDS**

B2C -E (Novel Hot Melt Extrusion), B2C -F (Hot Melt Fragmentation) and B2C-G (Activated Granulation)













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## **COMPONENTS**



#### HMES Conveyor unit (Chilled Air)

STEER offers HMES conveyor unit for various capacities. The conveyor unit has provisions for chilled air supply through vortex tubes and can be integrated with STEER HMES. The unit is with an independent drive and HMI.



#### **HMES Micro Feeder**

The volumetric micro feeder for research and development ensures consistent feeding into the extruder. The micro feeder is designed to provide high level of accuracy and repeatability.

STEER HMES micro feeder can be fully integrated with STEER OMICRON 10 Mini & OMICRON 12 and can be controlled using a single PLC. The Micro feeder is designed as per GMP standards and is easy to clean and dismantle.

The option to change different screws ensures that it can feed the most difficult materials used in the pharmaceutical research.



HMES.STEERWORLD.COM



#### INSTALLATIONS OF STEER EXTRUDERS & EPZ PRODUCTS / SERVICES

#### **SPANNING OVER 35 COUNTRIES**

BANGLADESH I BELARUS I BELGIUM I CANADA I CHINA I FRANCE I GERMANY I HOLLAND I INDIA INDONESIA I ISRAEL I ITALY I JAPAN I KINGDOM OF SAUDI ARABIA I SOUTH KOREA I MALAYSIA I MEXICO NEPAL I NIGERIA I PAKISTAN I POLAND I RUSSIA I SCOTLAND I SINGAPORE I SLOVENIA I SOUTH AFRICA SPAIN I SYRIA I TAIWAN I THAILAND I TURKEY I UAE I UKRAINE I UK I USA

# hot melt extrusion system

FOR PHARMACEUTICAL APPLICATIONS



S T E E R A N E W W O R L D

Currently, this technique is extensively used in pharmaceutical research and development for time

#### CONTENTS

- 01 SECTION 1 STEER H.M.E.S. AN OVERVIEW
- 10 SECTION 2 STEER H.M.E.S. OMICRON
- 18 SECTION 3 STEER H.M.E.S. OMEGA
- 24 SECTION 4 CHILL ROLLER

#### **INSERTS**

- ANNEXURE
- HME SPECIFICATIONS
- STEER PHARMA SERVICES & RESOURCES

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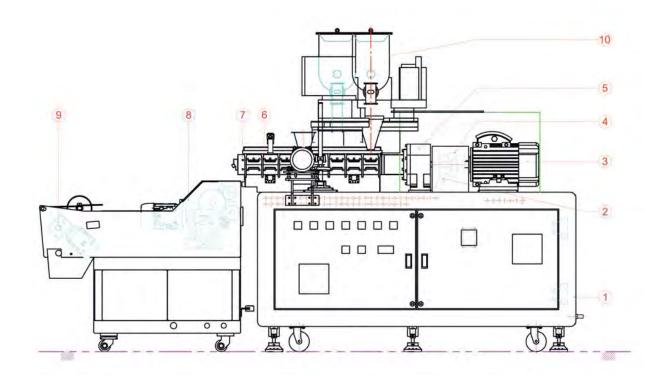
W W W . S T E E R W O R L D . C O M



## schematic overview

#### STEER OMEGA PHARMA TWIN-SCREW EXTRUDERS

- / MODULAR
- / COMPREHENSIVE
- / SCALABLE



- 1. MACHINE BASE
- 2. PROXIMITY SENSOR
- 3. MOTOR
- 4. TORQUE LIMITER COUPLING
- 5. GEARBOX
- 6. EPZ PARTS
- 7. DIE ASSEMBLY
- 8. CHILLER ROLL UNIT
- 9. FLAKERUNIT
- 10. GRAVIMETRIC FEEDER





- / MODULAR
- / COMPREHENSIVE
- / SCALABLE

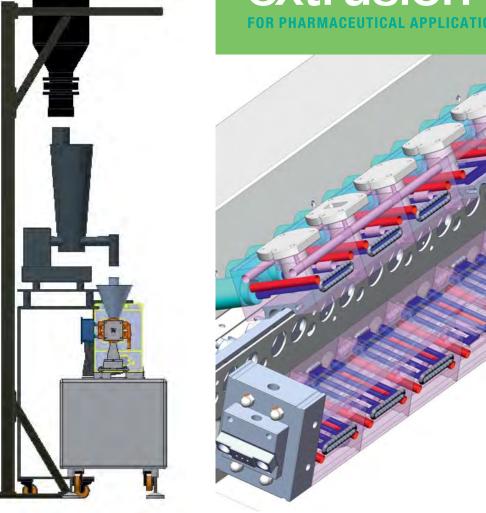






## STEER HMES

# hot melt extrusion system



- Hot excipient /API is metered onto the upper feed roll
- The feed roll are maintained at a desired temperature using a temperature control unit
- The speed of the rolls and conveyor belt are synchronized, no need of individual control
- Speed of the drive hardware can be varied from 0 to 2750 mm/min (110 in/min)
- The gap between the chill rolls can be adjusted from 0.5mm to 3mm in width depending on product requirements
- Wiping blades scrap the product film off of the chill roll in large flakes
- The flakes fall to the conveying belt for transport to the flaker
- The tension of the conveying belt is adjustable
- The conveyor belt mounting cartridge provides easy access to remove and replace belts between product types
- Product is transported off of the end of the conveyor and dropped into a rotating flaker
- The flaker speed is independently controlled and can be adjusted to provided the desired product consistency
- Modular in design, easy to relocate for storage or other uses
- Construction to cGMP standards
- 316 stainless steel construction for contact surfaces
- 304 stainless steel construction for non-contact surfaces
- Integrated flaker included on larger units, optional granulater on smaller units
- Food grade polyurethane conveyor belt
- Cartridge style conveyor mount for quick and easy belt replacement
- PLC based integrated controls can be mounted remotely or on the unit



- / MODULAR
- / COMPREHENSIVE
- / SCALABLE



capacity of 2 – 15 kg/hr and has an integrated flaker

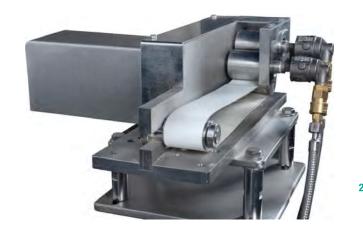


roll unit

features of operation

specifications





capacity of 4 – 50 kg/hr and has an integrated flaker





STEER H.M.E.S is a complete system with its core unit 'Hot Melt Extruder' having the STEER EPZ products like Screw Elements & Barrels; integrated appropriately with both up-stream and down-stream components like Micro Feeder, Split and Side Feeder, Refill Silo, Associated Platform, Chill Roll Unit, Chill Air Conveyor Unit, Pelletizer and Flaker. The system is modular, comprehensive and scalable.

S T E E R A N E W W O R L D

Pharmaceutical Compounding using Hot Melt Extrusion (HME) involves achieving a homogenous solid dispersion or solution by mixing and/or melting API with one or more recipients such as polymers, lipids, surfactants, diluents, lubricants, glidants, plasticizers and other modifiers for the purpose of stabilization, bioavailability enhancement, controlled release or taste masking and improved delivery especially in oral and trans-dermal systems.

- Dr. Babu Padmanabhan

Established by Dr. Babu Padmanabhan PhD [www.drbabupadmanabhan.com] in the year 1993 with a mission to achieve ascendancy in technology and new material development. STEER has grown since then to be a globally acknowledged leader in the self cleaning twin screw process technology catering to the pharmaceutical, plastic & food industry. STEER fulfills customer needs through its generation-next extruders that are well known for their 'varied applications, craftsmanship and engineering'. It is one of the most vertically integrated manufacturing company in the extruder industry.

STEER's Twin-Screw Extruders offer the best feeding ability, greatest energy efficiency and highest torque capability. STEER's Hot Melt Extrusion product offerings have occupied an enviable market position in the global pharmaceutical industry.



STEER offers multiple sizes of chill roll units for the pharmaceutical industry with capacity ratings from as low as 0.2 kg/hr up to 50 kg/hr, all constructed to cGMP standards. These units are designed to accept molten excepient/API produced by hot melt extrusion (HME) or other sources and quick chill the excipient in order to preserve crystalline active ingredients in an amorphous state for enhanced bioavailability. A film is formed on the upper roll and immediately chilled and deposited onto a conveyer belt below the chill roll where it is transported to a flaker or granulator for size reduction.

Research & Development

STEER H.M.E.S. OMICTON 10 FOR PHARMACEUTICAL R&D LAB

STEER HMES OMICTON 12

Pilot & Full Scale Production STEER H.M.E.S. OMEGA 20
FOR PHARMACEUTICAL PILOT PRODUCTION

STEER H.M.E.S. OMEGA 30
FOR PHARMACEUTICAL REGULAR PRODUCTION

STEER 

chill roll unit

STEER

hot melt extrusion system

**CHILL ROLL WITH INTEGRATED FLAKER IS** RATED FOR A CAPACITY OF 4 - 50 KG/HR



STEER manufactures HME extruders in sizes ranging from 10mm, with the capability to run feed rates as low as 10-15 grams per batch, to 70mm models with the capability to run rates as high as 250-300 kg/hr. All extruders are cGMP compliant. STEER is the only supplier in the industry to offer all extruders in both clam shell and segmented barrel configurations. All STEER pharma extruders are scalable making it possible to accurately translate R&D projects to a manufacturing scale, or reproduce a manufacturing process on an R&D scale extruder. STEER also provides ancillary HME equipment to the industry such as chill roll units, cooling belts, flakers, pelletizers, etc





#### Pharmaceutical Research & Development

## STEER H.M.E.S. OMICTON 10 FOR PHARMACEUTICAL R&D LAB [MINI]



#### R & D LAB

STEER HMES OMICRON 10 [MINI] offers the best platform for Universities and Pharmaceutical Companies doing hard core research on hot melt extrusion on NCE and/or applications requiring high potent API. OMICRON 10 is designed to handle very low volumes. The option of changing process section with four different Do/Di (1.27, 1.42, 1.55, 1.71) ratios to vary the shear rate makes OMICRON 10 the best extruder platform for pharmaceutical research.

## STEER H.M.E.S. OMICTON 12 FOR PHARMACEUTICAL R&D LAB & PILOT PRODUCTION



## R & D LAB AND PILOT PRODUCTION

STEER HMES OMICRON 12 is an excellent extruder for conducting feasibility / proof of concept studies in pharmaceutical research. With micro feeder and combinational downstream ancillaries, OMICRON 12 is a complete solution for scale up studies for the drug development. OMICRON 12 is well-known to process most of the excipients used in pharma research.

- / MODULAR
- / COMPREHENSIVE
- / SCALABLE

STEER's OMEGA PHARMA twin-screw extruder created for pharmaceutical applications is modular in design. The HOT MELT EXTRUSION SYSTEM consists of co-rotating fully wiping twin-screws and clamshell barrel. The key tasks of the extruder are mixing, homogenizing and degassing. Its modular design offers a choice of screw elements which allow altering the configuration of the intake, mixing and metering zones with respect to different applications. Flexibility, continuous operation process capability and higher energy efficiency make the OMEGA PHARMA HOT MELT EXTRUSION SYSTEM the ideal Pharma extruder.

- Conforms to GMP standards
- Clamshell or Segmented Barrel Jiffy Clamp design for easy cleaning
- Precise temperature control
- Custom upstream: Split/Side feeding, Refill Silos, Platforms
- Application based custom downstream: Chill Roll, Cool Air Conveyor, and Pelletizer
- Complete Validation support
- 21 CFR part 11 compliance
- High Throughput
- Plant engineering support
- Easy Cleaning and dismantling
- Inline Process Control (PAT)
- Better mixing capability
- Shorter residence time
- Reliable data logging
- Hot Melt extrusion formulations
- Solid Molecular dispersions
- Bio-availability Enhancement
- Taste Masking
- Sustained Release



#### Pilot and Full-scale Production



key features

omega 3

22

advantages

applications











## PILOT SCALE PRODUCTION EXTRUDERS

For Scale-up studies, Exhibit / Clinical batches, STEER HMES OMEGA 20 is the most suitable pilot scale extruder. OMEGA 20 is designed to comply with GMP requirements of automation, contact surface and cleaning.





## FULL SCALE PRODUCTION EXTRUDERS

STEER provides production scale HMES ranging from OMEGA 30, 40 and upto 70mm. STEER production scale extruders are manufactured to achieve high level of efficiently in throughput and crafted to offer ease of use and low downtime during product change over. High torque gear box, precise control over process parameters, ease of cleaning and validation are some of the key features of STEER's full scale production extruders.

- / MODULAR
- / COMPREHENSIVE
- / SCALABLE

#### STEER



#### **KEY ADVANTAGES OF STEER HMES**

- Assured melt quality
- Better mixing capability
- Easy cleaning
- Clamshell and segmented barrel design
- Precise control of process parameters
- Shorter residence time
- Continuous process
- Integration with PAT tools
- Audit trails
- Processing of temperature sensitive actives
- STEER patented elements for pharmaceutical materials
- The rewarding customer services through its dedicated STEER PSR division

- / MODULAR
- / COMPREHENSIVE
- / SCALABLE

STEER HMES OMEGA 20 is the most suitable pilot scale extruder for Scale-up studies, Exhibit / Clinical batches. OMEGA 20 is designed to comply with GMP requirements of automation, contact surface and cleaning.

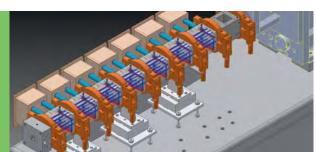
#### Pilot Scale

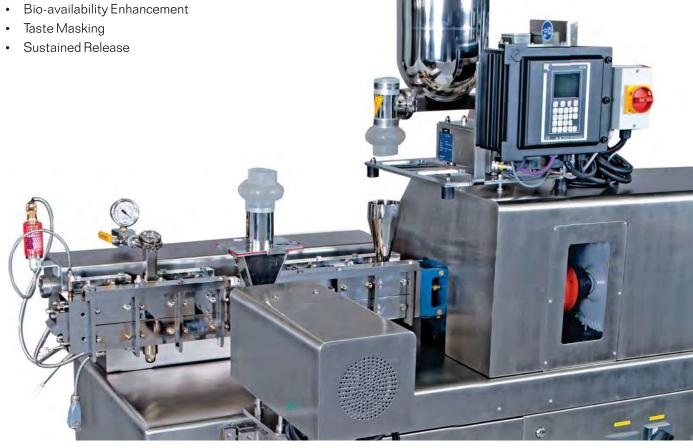
- Conforms to GMP
- Option of Clam Shell and Segmented Jiffy Clamp Barrel Design
- Upstream: Split/Side Feeding
- Downstream: Chill Roll Unit, Cool Air Conveyor, and Pelletizer
- Liquid/Gas injection
- Skid mounted
- Degassing
- Scalability
- Process Flexibility
- Easy Cleaning and dismantling
- Inline Process Control (PAT)
- Better mixing capability
- Shorter residence time
- Reliable data logging

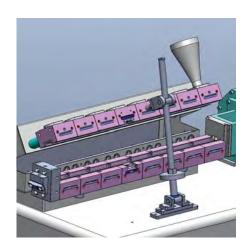
#### Exhibit batches

- Clinical batches
- Scale-up studies
- Solid Molecular dispersions









#### **CLAMSHELL BARREL**

STEER Clamshell barrel provides easy access to the Screw elements and reduces the cleaning time of the barrels and elements. This in turn reduces the change overtime and hence the formulation changing in STEER extruder is much more simple and effective.



**CHILL ROLL OUT ZONE** 



key features

omega 20

20

advantages

applications



STEER the global leader in EPZ Products like Screw elements, Shafts and

STEER SCREW ELEMENTS • STEER SHAFTS • STEER BARRELS & LINERS

The Extruder Processing Zone (EPZ) is the 'heart' of a Co-rotating Twin-Screw Extruder that helps to achieve the desired performance. STEER screw elements ensure a fully wiping profile for any lead of screw, any number of starts and any machine parameter.

Barrels provide a host of services including replacement of screws



STEER is a pioneer and global leader in EPZ products like Screw-elements, Shafts, Barrels.

STEER offers special screw elements (patented) to provide unique solutions for low bulk density powders, highly viscous melt, temperature sensitive API's, high drug load formulations.



## FOR HIGHER INTAKE STEER SFV ELEMENTS



FOR HIGHER INTAKE (SPECIAL)
STEER RFV ELEMENTS



FOR ENHANCED MIXING STEER FKB ELEMENTS

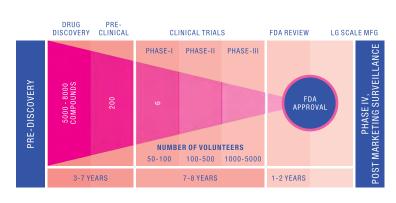


FOR EFFICIENT MELTING
STEER FME ELEMENTS



STEER HOT MELT EXTRUSION SYSTEMs [H.M.E.S] for pharmaceutical applications are available for all stages of product life cycle: From research, preclinical, pilot production and full-scale production.

STEER has a fully dedicated PHARMA SERVICES & RESOURCES [PSR] facility to serve the ever growing pharmaceutical industry that aspires to utilize the HME technology to its optimum level.



W HMES.STEERWORLD.COM
E HMES@STEERWORLD.COM





# pharma research & development

STEER H.M.E.S. OMICTON 10
FOR PHARMACEUTICAL R&D LAB [MINI]

STEER H.M.E.S. OMICTON 12
FOR PHARMACEUTICAL R&D LAB & PILOT PRODUCTION

10





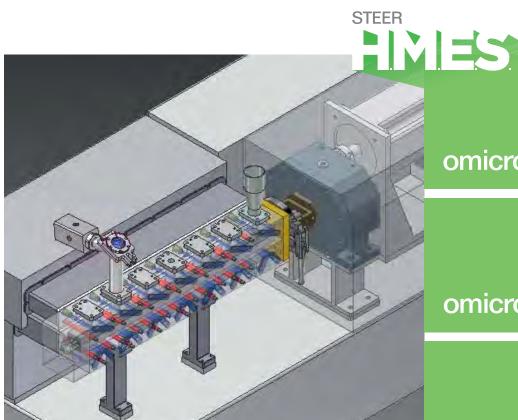
# pilot & full scale production



STEER H.M.E.S. OMEGA 20
FOR PHARMACEUTICAL PILOT PRODUCTION

STEER H.M.E.S. OMEGA 30
FOR PHARMACEUTICAL REGULAR PRODUCTION





omicron 10 [mini]

omicron 12

applications



- Minimum quantity -40gm
- Flexibility of feeding in any zone / liquid injection
- Modular/configurable screw elements
- Length 42 D
- 8 Heating and cooling zones with vent ports o Barrel Liner SSX15 TN
- STEER EPZ Products
- Easy cleaning and changeover
- Low material loss
- Inline process control
- Easy scale up
- Processing of temperature sensitive API

- Hot Melt Extrusion formulations
- Research & Development projects



pharmaceutical research & development and pilot production

STEER H.M.E.S. OMICTON 12
FOR PHARMACEUTICAL R&D LAB & PILOT PRODUCTION

## pharma twin-screw extruders

OMICRON 12 PHARMA is a co-rotating twinscrew laboratory extruder, specifically designed and developed for the Pharmaceutical industry. The ability of this HOT MELT EXTRUSION SYSTEM is to generate outstanding dispersive and distributive mixing. It can produce material at an extremely low output rate, which helps in lowering the cost of development of new products. OMICRON 12 PHARMA offers the widest flexibility available in today's market for Research & Development projects with the ability to be customized for any given application.







STEER HMES OMICRON 10 [MINI] offers the best platform for Universities and Pharmaceutical Companies doing hard core research on hot melt extrusion on NCE and/or applications requiring high potent API. OMICRON 10 is designed to handle very low volumes with the option of changing process section with four different Do/Di (1.27, 1.42, 1.55, 1.71) ratios to vary the shear rate makes OMICRON 10 the best extruder platform for pharmaceutical research.

STEER HMES OMICRON 12 is an excellent extruder for conducting feasibility / proof of concept studies in pharmaceutical research. With micro feeder and combinational downstream ancillaries OM 12 is a complete solution for scale up studies for the drug development. OM 12 is well-known to process most of the excipients used in Pharma research.

- Bioavailability enhancement
- · Sustained or controlled release
- Taste masking
- Potent compounds (oncology, narcotics) processing dust reduction
- Stabilizing moisture sensitive drugs
- Solvent free processing
- Content uniformity for very low dose drugs







# pharmaceutical research & development



STEER HMES OMICTON 10 FOR PHARMACEUTICAL R&D LAB

## pharma twin-screw extruders

The OMICRON 10 Mini is the pharmaceutical industries smallest scalable extruder for HME development. The design and utility of the OMICRON 10 Mini makes it the most versatile and user friendly platform for low volume HME applications. Features which include tight tolerances, eliminated dead space, and low inventory die head make it ideal for the development of pharmaceutical applications requiring costly excipients and high potency API's.

14





**FEATURES** 

nctional

FEATURE

**FEATURES** 

mechanica

Originally developed to support the growth of pharmaceutical research utilizing PLGA, a costly excipient approved by the FDA for oral and parenteral sustained release applications

Small footprint of only 650L x 350W x 300H and less than 45kg, the extruder easily fits on a laboratory bench for portability and flexibility of use

Effective in handling small batch quantities -10g to 15g

Novel design features eliminate the need for complex procedures to clean and maintain the extruder

• All service components are easily disassembled and reassembled manually without the use of special tools

Unlike other HME "micro" extruders rated at similar throughput rates, the OMICRON 10 MINI is truly scalable to larger HME extruders

The drive motor is directly coupled to the gearbox eliminating the need for a drive belt

Easy to use Tri-Clover Clamps are used to join the barrel assembly to the gearbox, and to attach the die head to the extruder barrel assembly

• Through the use of Tri-Clover Clamps the barrel assembly can easily be removed in minutes

The barrel liner can be removed from the barrel housing for inspection, cleaning, or replacement

Screw shafts are quickly and easily removed and installed through the use of a "cross pin". By simply pulling (retracting) the cross pin from the coupling housing the shafts can easily be extracted, and shafts are reinstalled by simply inserting them into the coupling housing and pushing (inserting) the cross pin into the housing

Cooling lines have quick connect fittings to facilitate barrel removal, and feature FDA approved hose construction

The one piece machined screw shaft (not segmented) are custom designed to conform to the profiles required for specific customer applications (STEER can assist customers with design support at no cost)

• The OMICRON 10 MINI is compatible with all small scale STEER ancillary components such as pelletizers, cooling belts, chill rolls (smallest in the Pharma industry), etc

Clamshell design enables quick access to the process section for disassembly and cleaning, as well as enabling rapid inspection of the process section during hot melt extrusion to support process technology development (R&D)

The barrel liner is easily removed without the use of tools to facilitate quick disassembly, cleaning and reassembly. The two halves of the clam shell barrel are rigidly clamped together by toggle clamp system

Screws are also easily removed for cleaning and inspection by simply retracting a cross pin

One piece machined screws shaft (vs.multi-piece segmented screws) eliminate the opportunity for cross contamination from active ingredients becoming trapped between segmented screw elements where they can later re-enter the process section, this is a particularly important feature for processing HPAPI's

• The material of construction for the shafts and barrel liner is of Surgical Stainless Steel. All exposed contact surfaces are of SS316L including the gearbox housing. There are four heating/cooling temperature control zones. All zones have water cooling, both upper and lower barrel sections are water cooled as opposed to many small pharma extruders in which only partial barrel sections are water cooled or that utilize air cooling

• The OMICRON 10 MINI has multiple dry feeding ports and liquid injections ports. There are vacuum and atmospheric venting options. The HMI can be mounted remotely to support the isolation of the extruder within a controlled environment, or it can be attached to the extruder for local operation. The HMI is easily removed from the extruder to enable aqueous cleaning of the entire equipment in situ without the presence of the control module