

Category

Best Startup

Product/Solution Name

Rondol "All-in-one"

Date of Approval

2021-03-16

Indications

"Indications" for pharmaceutical products produced using a twin-screw extruder technology can span across a broad range of diseases and conditions. Although the machine itself doesn't have a specific therapeutic indication, the extrusion process it performs can support the production of:

Controlled-Release Formulations: These are used to administer medication in controlled amounts over a specified period. Indications for these drugs can range from chronic conditions like cardiovascular diseases, diabetes, and psychiatric disorders, where a steady state of the drug is required.

Fast-Release or Immediate-Release Formulations: Used when rapid onset of action is needed, such as in pain relief or allergic reactions.

Orally Disintegrating Tablets (ODTs): These are useful for patients who have difficulty swallowing, which includes a broad range of indications, particularly in pediatrics and geriatrics.

Bioactive Implants: For localized drug delivery, in indications such as localized cancer treatment, contraception, etc.

Targeted Drug Delivery Systems: These are used in precision medicine, especially for oncology treatments where targeted drug delivery can help minimize side effects and improve efficacy.

Pediatric and Geriatric Formulations: Specific formulations that consider the unique pharmacokinetics and pharmacodynamics of these patient populations, as well as ease of administration.

So, while the twin-screw extruder itself does not have indications, it is a crucial tool in producing formulations for a wide variety of therapeutic indications across different patient populations and disease conditions.

Therapeutic Categories

Twin-screw extruders play a vital role in numerous therapeutic categories, advancing pharmaceutical development and manufacturing processes across the board. The versatility of extrusion allows for the efficient production of various dosage forms in a range of therapeutic areas.

Oral Solid Dosage Forms: In the domain of oral solid dosage forms, twin-screw extruders are frequently used to manufacture granules, pellets, and tablets. This includes immediate-release, modified-release,

and targeted-release formulations, enabling precise control over drug dissolution and absorption profiles. Therapeutic areas ranging from cardiovascular to CNS disorders to diabetes benefit from these oral delivery systems.

Oncology: In oncology, extrusion technology is crucial for the formulation of anti-cancer drugs, particularly in creating nano and micro-sized drug particles. This facilitates improved drug targeting and reduced side effects, essential factors in cancer therapeutics.

Pediatric and Geriatric Medications: For special populations like pediatrics and geriatrics, twin-screw extrusion assists in the formulation of palatable and easy-to-swallow medicines. Techniques like melt extrusion can be used to create orally disintegrating strips or mini-tablets that offer dosing flexibility and patient convenience.

Biopharmaceuticals: For biopharmaceutical products, such as proteins and peptides, twin-screw extrusion can be used in the encapsulation processes to protect these delicate molecules from degradation, enhance their stability, and control their release.

Poorly Soluble Drugs: Twin-screw extrusion is also pivotal in enhancing the bioavailability of poorly soluble drugs. By producing solid dispersions or nano-formulations, extrusion technology can increase dissolution rate and thus improve drug absorption.

Transdermal and Topical Applications: Extrusion technology is useful in the production of transdermal patches and topical formulations. It allows for the uniform distribution of active pharmaceutical ingredients (APIs), ensuring consistent drug delivery.

In conclusion, twin-screw extruders are essential tools in modern pharmaceutical manufacturing, touching upon a diverse array of therapeutic categories. Their ability to enable advanced formulation techniques, from solid dispersion to encapsulation, makes them valuable in addressing the ongoing challenges of drug delivery and patient care.

Background information and need for solution/product

The pharmaceutical industry is increasingly driven by the need to create more effective and patient-centric drug formulations. These innovative formulations demand sophisticated and versatile manufacturing equipment that can handle a wide variety of processes, among them hot melt extrusion (HME).

HME is a popular manufacturing process used in the creation of various dosage forms. These include controlled-release tablets, orally disintegrating tablets, bioactive implants, fast-release tablets, and other targeted drug delivery systems. Moreover, it can handle a broad spectrum of materials, from thermally stable active ingredients to heat-sensitive ones, and enables the incorporation of poorly soluble drugs into suitable carriers, thereby enhancing their bioavailability.

The need for a solution arises from the complexity and diversity of the drug formulation processes, which require specialized and highly adaptable machinery. Here is where the Rondol All-in-one twin screw extruder comes into play.

The All-in-one twin screw extruder from Rondol is designed specifically for the pharmaceutical

industry. Its versatility enables it to handle both research and development and small to medium-scale production. Moreover, it meets the strict regulatory standards of the industry, ensuring high-quality and compliant production. This machine is built to offer precision, reliability, and operational ease, making it an ideal solution for pharma manufacturers seeking to produce advanced drug formulations.

With its capacity to perform various processing tasks efficiently, Rondol's twin screw extruder is an essential tool for modern pharmaceutical manufacturing. The use of such a machine helps to streamline the manufacturing process, reduces waste, and allows for more versatile and adaptable production, ultimately resulting in better, more effective treatments for patients.

History of the development of the solution/product

Rondol embarked on the development of the All-in-one twin screw extruder back in 2012, responding to the evolving needs and demands of the pharmaceutical industry.

Recognizing the transformative potential of twin-screw extrusion technology, Rondol aimed to bring a solution specifically designed for pharmaceutical applications. This technology, which was already proven in other industries such as food and plastics, offered substantial benefits in drug formulation and delivery, including the ability to improve the solubility and bioavailability of medications.

The process of developing the All-in-one twin screw extruder was meticulous and detail-oriented. The Rondol team undertook extensive research and design activities, aiming to create a machine that was not only robust and efficient but also versatile and user-friendly. The goal was to accommodate the broad spectrum of materials and processes present in pharmaceutical manufacturing.

Through years of consistent efforts, the All-in-one twin screw extruder was introduced. The machine was equipped to meet and exceed the stringent regulatory requirements of the pharmaceutical industry, ensuring the high-quality and compliant production of drugs. It was designed with versatility in mind, capable of handling a wide array of formulations and manufacturing processes.

Ever since its introduction, the All-in-one twin screw extruder has been subject to continuous improvement and adaptation. Rondol is committed to incorporating the latest technological advancements and adapting to the changing needs of the industry. This dedication to continual progress ensures that the All-in-one twin screw extruder remains an innovative, state-of-the-art solution for pharmaceutical manufacturing.

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

The All-in-one twin screw extruder from Rondol represents a significant innovation in pharmaceutical manufacturing due to its capacity to increase the efficiency of drug formulation and delivery, allowing for more effective therapeutic solutions.

What sets this technology apart is its ability to handle complex formulations, enhance drug solubility, and improve bioavailability. These features allow for a more effective delivery of active pharmaceutical ingredients (APIs), which means more efficient therapies with potentially fewer side effects. The precision and control that the All-in-one machine provides during the extrusion process can also help to reduce drug development costs, an economic benefit that could have broad implications for the

pharmaceutical industry.

Moreover, the versatility and adaptability of the All-in-one twin screw extruder open up new horizons for future pharmaceutical research and development. The machine's flexibility to work with a wide range of materials and processes encourages innovation in drug formulation, enabling the development of more effective and potentially life-saving treatments. It could play a significant role in the development of personalized medicine, for example, where treatments are tailored to individual patients' needs.

The improvement in the human condition that this innovation can contribute to is multi-faceted. By enhancing drug solubility and bioavailability, patients can receive more effective treatment. More efficient manufacturing processes can potentially reduce drug costs, making treatments more accessible. Furthermore, encouraging innovation in drug formulation can contribute to the development of novel treatments for diseases that are currently difficult to manage.

The All-in-One Extruder by Rondol offers an impressive feature with its compact design, occupying only 0.5 m² of space in high-capital intensity clean rooms. This small footprint enables efficient utilization of valuable clean room real estate, optimizing production capabilities while adhering to stringent regulatory requirements. The machine's ability to deliver outstanding performance within a limited space makes it an ideal solution for pharmaceutical manufacturers looking to achieve both operational excellence and cost-effectiveness in their clean room environments.

In short, the All-in-one twin screw extruder from Rondol offers an innovative solution with the potential to significantly improve pharmaceutical manufacturing, enhance patient care, and contribute to future advancements in the field.

Please provide appropriate references (ie Pubmed links)

Reference (see attached) :

- de Margerie, V., Boulet, P., & Gallas, M. (2023). Extrusion for pharma applications: An update. SPE Polymers. Retrieved from <https://4spepublications.onlinelibrary.wiley.com/doi/10.1002/pls2.10081>

- de Margerie, V., McConville, C., Dadou, S. M., Li, S., Boulet, P., Aranda, L., Walker, A., Mohylyuk, V., Jones, D. S., Murray, B., & Andrews, G. P. (2021). Continuous manufacture of hydroxychloroquine sulfate drug products via hot melt extrusion technology to meet increased demand during a global pandemic: From bench to pilot scale. *International Journal of Pharmaceutics*, 605, 120818. <https://doi.org/10.1016/j.ijpharm.2021.120818>

Proof of concepts (see attached) :

- Proof of Concept 1: RONDOL SEQENS: Reformulating Aspirin

In a collaborative effort between Rondol and Seqens in 2021, a proof of concept was conducted to reformulate AcetylSalicylic Acid (ASA), commonly known as Aspirin, using Hot Melt Extrusion (HME) on Rondol's "All-in-One" vertical twin-screw extruder. The study successfully achieved fully amorphous ASA at loadings of up to 45% w/w. The remarkable finding was the long-term stability of the amorphous form, maintained even six weeks after manufacture. These results highlight the potential

of Hot Melt Extrusion (HME) using Rondol's All-in-One extruder to optimize dosing of various drugs, particularly those with high initial dosing requirements and toxicity concerns, across a broad range of diseases.

- Proof of Concept 2: RONDOL, BASF & QUB – Child Friendly Anti Malaria

The collaborative project between Rondol, BASF, and QUB (Queen's University Belfast) focused on developing a robust, child-friendly fixed dose combination (FDC) for antimalarial agents using Hot Melt Extrusion (HME) on Rondol's "All-in-One" vertical twin-screw extruder as a continuous manufacturing platform. The aim was to address the poor solubility and bioavailability issues of the Artemether and Lumefantrine (AT-LM) FDC, which is the recommended antimalarial treatment endorsed by the World Health Organization (WHO). The successful utilization of Hot Melt Extrusion (HME) technology enabled the development and manufacturing of a child-friendly FDC formulation, offering improved dosing compliance, minimized resistance development, reduced side effects, and cost-effective continuous supply of the antimalarial agents to malaria-endemic countries.