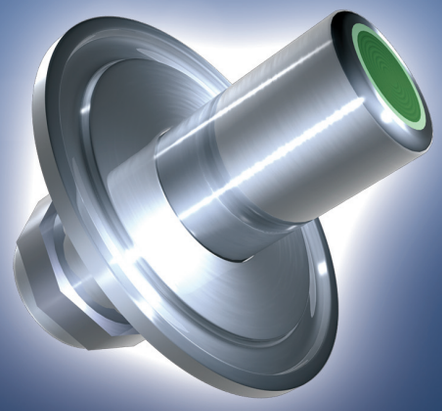
FORMULATION & PROCESS ENGINEERING

ACCELERATE YOUR DEVELOPMENT, TECHNICAL TRANSFER AND SCALE-UP

EFFUSIVITY SENSOR PACKAGE



Real Time Information Right out of the Box

Mathis ESP™ (Effusivity Sensor Package) offers an incremental 'analytical window' on physical properties, such as lubrication, drying, roller compaction and uniformity – in real time. It accelerates your development, process engineering, technical transfer and scale-up by dramatically reducing your reliance on time consuming, intrusive, laboratory and in-process test methods such as HPLC and LOD. Effusivity does not require the comprehensive database of material characteristics necessary with other technologies. Mathis ESP is simple to use, requires minimal training, and can be up and running at your facility right out of the box.

Explore More Variables: More Thoroughly and Faster

Mathis ESP offers you instantaneous characterization of your formulations and processes that supplement, compliment, or correlate to other analytical and physical test data. Effusivity provides results rapidly – so you can manipulate your process variables one factor at time, or in conjunction with multivariate experimental designs – and respond immediately to what you've learned. Because effusivity is not a chemical property, you are able to work out some of your processing issues on placebo trials without dipping into your precious supply of active ingredient.

Reduce the Delays and Expense of Analytical Testing

Timing is critical in formulation development and scale-up. Effusivity offers you a competitive advantage – speed. Mathis ESP helps you get to market faster, and maintain more direct control over the pace and budget of developing a formulation and taking it through to production readiness. Reduce the amount of expensive and time consuming analytical laboratory testing with real time effusivity measurements you can conduct yourself. Imagine the value to your organization of launching a product even one week sooner.

Simplify Scale-Up with Accurate End Point Information

Mathis ESP dramatically reduces the complex calculations, engineering, and time required to scale-up formulations. Using real time data, it provides scalable end point information that can follow a process from developmental bench scale to full size commercial production. Mathis ESP is a process analytical tool that allows you to establish and define your critical process parameters with knowledge – not a stopwatch.

Mathis *ESP*

A Revolutionary New Analytical Window

Mathis ESP is a powerful, new tool for formulation development and production scale-up. It is simple to use, and allows you to optimize formulations quickly and cost-effectively. Effusivity is an end-to-end tool that can be used to evaluate ingredients in the lab – and when you and the product are ready – it can be integrated into production equipment. The ESP is configured with a 'lite' historian database and a laptop to meet the analysis needs of development scientists. When process rules are established, they are simply incorporated into the ruggedized, integratable, HMI-driven ESP system for the plant. The output from Mathis ESP can supplement your release protocols or replace them with accurate end point data. The plant depends on new product being transferred with 'quality by design'. ESP helps you address their needs by generating a more complete understanding of the product and processes.

The ROI of Real Time Knowledge

By providing you with timely information, Mathis ESP gives you ingredient-specific knowledge to help you identify better excipient combinations. For process engineers and scientists, it provides process insights and end points – and, hence, fewer problems. Mathis ESP offers rapid return on investment by reducing the expense of lab testing, and allowing more comprehensive process engineering and scale-up. Potential problems can be thoroughly investigated, identified and corrected more quickly, and well before production. In the formulation world, the cost of Mathis ESP equipment is easily recuperated in under a year with saved analytical time.

Beyond that, with a successful transfer of a robust product, there are fewer production batch failures and associated costs of root cause analysis. By reducing your analyst:scientist ratio, it increases your project throughput, and thus the department profitability. When competition is stiff for projects, having a proven success record often justifies a group's existence.

The Right Tool in the Right Hands

- Designed for easy mobility between several processes. Blend today. Dry tomorrow.
- Accurate characterization of materials that is highly sensitive to changes in particle structure, packing & particle connection, and composition
- Real time, minute-by-minute effusivity data from your process equipment
- Rigorously reviewed by standardization organizations in the creation of the ASTM E55 (PAT) standard and USP chapter <1073>
- Does not require a comprehensive ingredient characterization database
- Easy-to-use Windows®-based software for real time result viewing and a complete database of all results for trending and correlation
- System software allows 21CRFpart11 compliance but provides the flexibility of full data export to Excel®
- Retrofitting, integration, installation, validation and training are provided as a simple, one-stop, bundled solution

Better Formulations, Blends and Blend Lubrication Levels

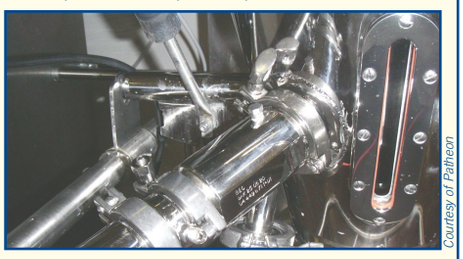
Mathis ESP allows you to explore excipient combinations quickly and easily. It gives you the power to accurately determine the end point for optimal blend uniformity and lubrication. Mathis ESP lets you to perform blend time challenges without stopping your blender, thieving samples, and compromising test results by sub-sampling ingredients for HPLC analysis. At scale-up, effusivity end points can be applied to any size and type of blending equipment – the effusivity for optimal uniformity and lubrication in a 16-quart blender is the same as for a 40 cubic foot blender. Sensors can be easily added to existing equipment through a simple cover retrofit.

Courtesy of Tote

Effusivity pinpoints significant events in your blending process – the end point for optimal uniformity, as well as the onset of de-blending, shear and attrition. If HPLC analysis is required, you can extract correlating thieve samples when these critical blend events occur instead of at predetermined times.

Detailed Drying Profiles and End Points

Mathis ESP eliminates the inaccuracies of stopping and starting your fluid bed dryer to perform multiple in process tests such as Loss On Drying (LOD). With the small batches that are typical in formulation, you don't have to worry about how the volume of extracted material is influencing the drying process and product uniformity. With effusivity, it is possible for the material to never leave the process. You can compile minute-by-minute profiles of product moisture content while your dryer is running. Effusivity correlates well with LOD and has comparable sensitivity (down to 0.25% moisture). Mathis ESP also reveals when your drying cycle begins to produce unwanted 'fines,' allowing you to alter dryer settings for consistent and repeatable mean particle size upon completion.

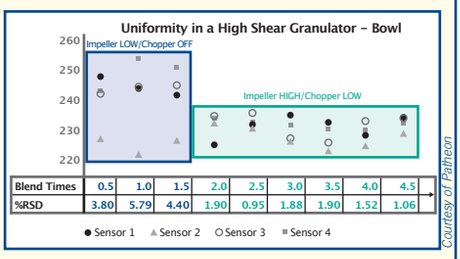


Courtesy of Patheon

A fluid bed dryer equipped with an ISOLOK™ sampler and ESP sensor provides highly detailed drying profiles and eliminates the need to stop the drying cycle, thieve samples, and perform time consuming LOD tests.

Quality by Design for Improved Robustness

By allowing you to quickly and easily evaluate your processes before scale-up, Mathis ESP lets you proactively explore potential manufacturing bottlenecks, optimize them, and prevent defective batches. For example, effusivity was used to assess functional excipient uniformity in a high shear granulation, and it immediately revealed that homogeneity was compromised when the equipment was operated at less than optimal process parameters. Effusivity allowed optimized granulator settings to be determined instantly during development and prior to validation and commercialization. More importantly, it facilitated better process understanding by providing insights that might not have otherwise been explored.



Courtesy of Patheon

Mathis ESP provides a revolutionary, real-time window into your processes, such as how uniformity is affected at various settings of a high-speed granulator. It accelerates formulation, process engineering and scale-up – and allows you to do so cost-effectively.

Consultation.

Contact us to find out how the Mathis ESP can accelerate your development, process engineering and scale-up.

1-866-425-3637 **www.ctherm.com**

C-Therm Technologies Ltd.

Formerly Mathis Instruments Ltd.