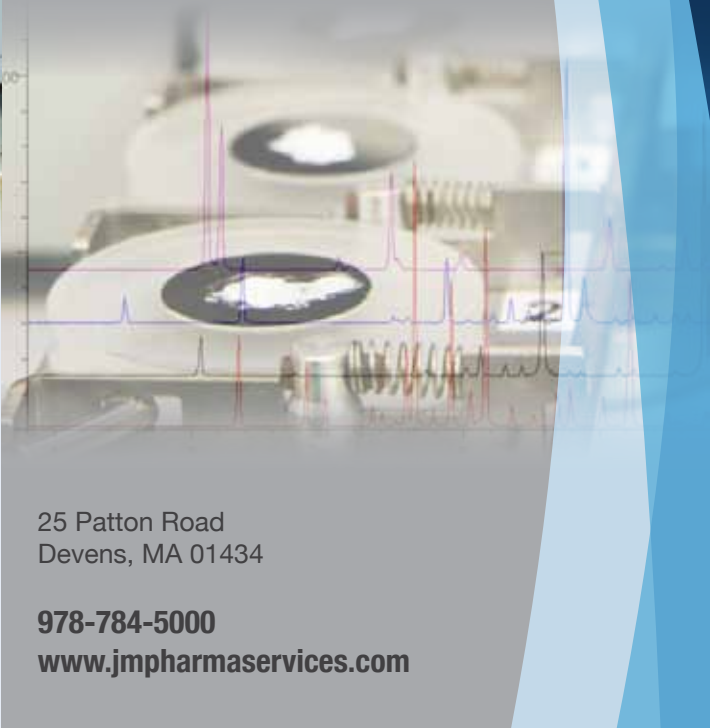




Johnson Matthey Pharma Services

Solid Form Screening

*Salt Selection, Polymorph
Screening, and Crystallization
Development*



25 Patton Road
Devens, MA 01434

978-784-5000

www.jmpharmaservices.com



Johnson Matthey
Pharma Services

Why is Solid Form Screening Important?

Consistency and quality of any active pharmaceutical ingredient (API) starts with solid form screening.

Because the majority of APIs exhibit polymorphism, **the FDA requires polymorphic studies** be conducted prior to NDA filing.

By studying and understanding the polymorphs of the API, and/or selecting the most viable salt, **we deliver manufacturing consistency for our clients, better control of clinical supplies, and broader IP protection.**



Identifying a viable salt and/or co-crystal greatly improves the hygroscopicity, solubility, and melting point range of your API.

Solid Form Screening & Crystallization Process Overview

Our highly skilled staff will conduct hundreds of scientifically crafted experiments to seek out the existence of polymorphs and produce viable salt candidates.

Services include:

Batch Profiling

- Full characterization of starting solid
- Solubility assessment in a range of solvents

Salt Screening/Co-Crystallization

- Selection of counter ions and/or co-formers
- Extensive characterization of the resulting products and selection of the most viable salt



Polymorph Screening

- Scientific design and execution of polymorph screening experiments
- Generation of amorphous material
- Polymorph scale-up and full characterization
- Relative stability mapping of different forms

Crystallization Development

- Evaluate the impact of solvent on morphology
- Evaluate the cloud point and metastability zone
- Investigate the effect of crystallization parameters and seeding on final particle size distribution and morphology
- Develop an optimal crystallization and isolation process



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For over 40 years, Johnson Matthey has guided its partners through every stage of drug development, from drug discovery through commercialization.

The recent addition of Solid Form Screening to our portfolio of services further enhances the breadth and quality of our offerings, and provides another valuable asset to our partners.

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*— Jay Reddy, General Manager
Johnson Matthey Pharma Services*

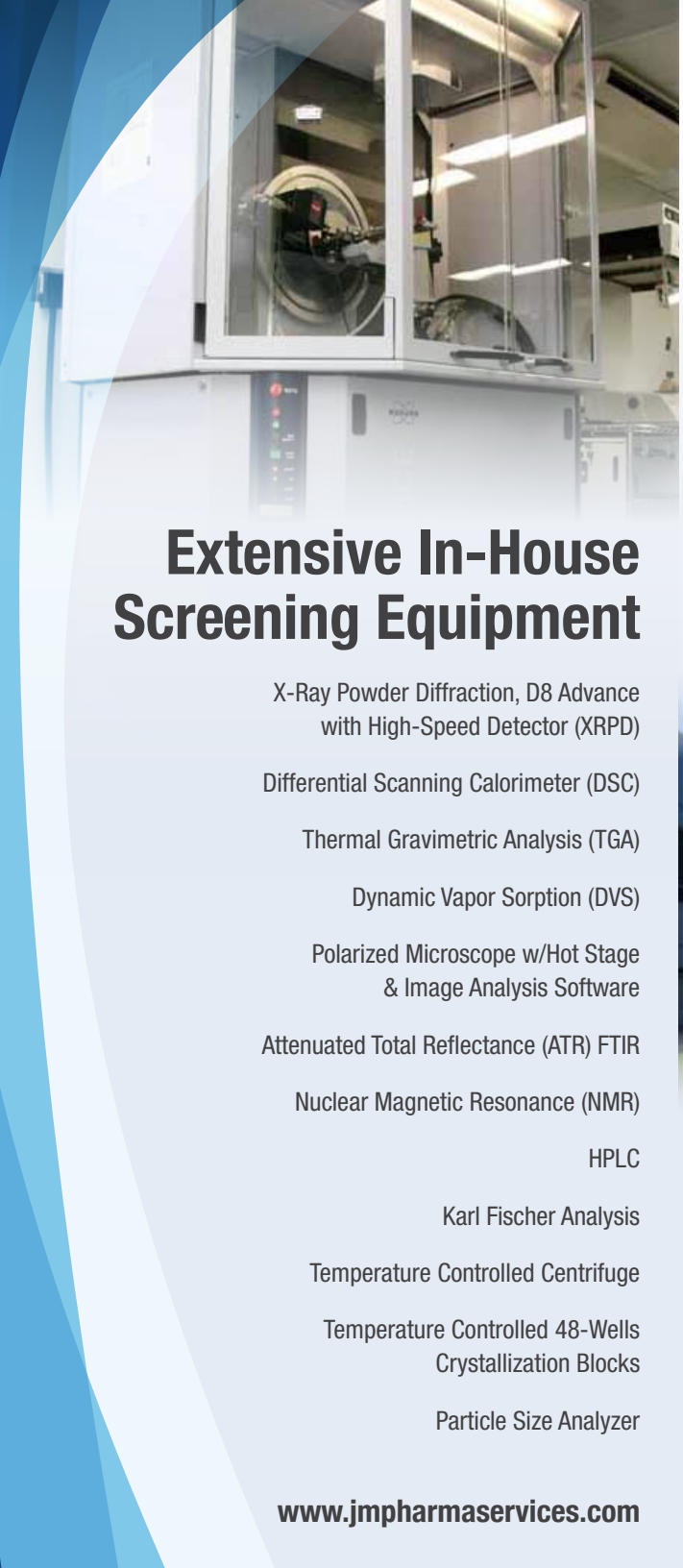
The JMPS Advantage

- Our in-house Process Development and Solid Form Screening services keep your project in one place, with one team, without interruptions.
- We have the ability to handle highly potent compounds up to SafeBridge® Category 4, and Controlled Substances Schedule I-V.
- Our vertical integration allows for an efficient and economical process scale-up.
- We provide excellent project management and regular communication with our clients.

To learn more, contact us at:

978-784-5000

www.jmpharmaservices.com



Extensive In-House Screening Equipment

X-Ray Powder Diffraction, D8 Advance
with High-Speed Detector (XRPD)

Differential Scanning Calorimeter (DSC)

Thermal Gravimetric Analysis (TGA)

Dynamic Vapor Sorption (DVS)

Polarized Microscope w/Hot Stage
& Image Analysis Software

Attenuated Total Reflectance (ATR) FTIR

Nuclear Magnetic Resonance (NMR)

HPLC

Karl Fischer Analysis

Temperature Controlled Centrifuge

Temperature Controlled 48-Wells
Crystallization Blocks

Particle Size Analyzer

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Superior Project Management

Your project team will consist of accomplished scientists proficient in solid state technologies and molecular polymorphism, with over 10 years of industry experience that includes crystallization expertise and thermodynamic & kinetics modeling.

They will effectively plan and perform comprehensive characterization and screening experiments on your API, including salt screening, crystallization, and process development for small and large molecules.

Our goal is simple: to provide you with customized solutions that lead you to reach your next milestone successfully.



At JMPS, we provide you with extensive chemistry services and unique technologies that span every phase of the drug development process, from discovery to commercial API production.



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