

**NATOLI**  
**SCIENTIFIC**

a division of Natoli Engineering Company, Inc.

[natoli.com](http://natoli.com)

# CUSTOMIZED SOLUTIONS TO MEET YOUR TABLETING CHALLENGES

Natoli Scientific's research, experimentation, and tableting expertise provides proactive solutions to your most difficult tablet compression challenges.

We offer comprehensive services to improve processes so you can decrease development times and avoid scale-up challenges and common manufacturing issues, such as sticking, picking, capping, and lamination.

Natoli Scientific's worldwide footprint includes facilities in St. Charles, Missouri, and Telford, Pennsylvania;

partnerships with universities in Long Island, Karachi, and Singapore; as well as technical representatives across Europe and Southeast Asia.

Whether you are just starting out with a product concept or you need troubleshooting for a product already in production, Natoli Scientific experts offer solutions and recommendations every step of the way!

## WE SUPPORT YOU FROM START TO FINISH

### FORMULATION DEVELOPMENT

Formulation development, modification, and testing services including:

- Development strategies
- Scalability solutions
- Compaction simulation

### ANALYTICAL SERVICES

Formulation analysis services including:

- API characterization
- Stability testing
- Method validation protocols
- Dissolution testing

### DATA ACQUISITION SYSTEMS

Natoli AIM™ Instrumentation and software upgrades  
NP-RD10A Single-station tablet press  
NP-RD30 Rotary development & scale-up tablet press

### TABLET PRESS & CALIBRATION SERVICES

Meet regulatory compliance with tablet press calibration services:

- Instrumented tablet presses & calibration
- Preventive maintenance services
- Tablet press assessment

### TECHNICAL TRAINING CENTER

Regularly scheduled and customized technical training courses provide:

- Classroom and hands-on learning
- On-site and off-site availability

### TOOLING RECOMMENDATIONS

Tool steel, material, and coating recommendations to resolve tablet sticking and picking issues.

### PRODUCTION/ MANUFACTURING

Small batch non-GMP CDMO support/services

*We give you results,* not predictions.

Natoli Scientific helps you avoid or solve issues that may arise during tablet compression, whether you're in the initial stages of research and development or troubleshooting an existing formulation.

We take a proactive approach to formulation development. Natoli Scientific actively looks for possible indicators during development that may impact scale-up and commercial production.

By identifying issues earlier in the process, we can recommend solutions to help you avoid time-consuming troubleshooting and reduce long-term costs. Natoli Scientific's team of experts will work with you to find the options and solutions that will best serve your objectives.

Our lab equipment is available for on-site rental, should you wish to test your formulations yourself.

#### Equipment Available for Use:

- *Presster compaction simulator*
- *FT4 powder rheometer*
- *Instrumented Natoli NP-RD30 rotary scale-up tablet press*
- *Instrumented Natoli NP-RD10A single-station tablet press*
- *Instrumented Natoli NP400 pilot/manufacturing scale rotary tablet press*
- *Roller compactor*
- *High shear granulator*
- *Milling (hammer, oscillating, & cone)*
- *Tablet coating pan system*
- *Bulk/Tap density tester*
- *Helium pycnometer*
- *Moisture analyzer*
- *Sonic Sieve tester*
- *Friability tester*
- *Disintegration baths*
- *Tablet hardness/ breaking force*
- *Gram and analytical balances*
- *V blenders*





# FORMULATION DEVELOPMENT & MODIFICATION

Developing a robust tablet formulation that is successfully scaled up to product manufacturing can be challenging. In fact, many manufacturing issues can be traced back to the formulation. At Natoli Scientific, we have developed a rigorous and creative stepwise approach to pro-actively identify mechanical deformation properties and issues with an API that affect processability.

As a critical first step, Natoli Scientific evaluates the characteristics of your formulation to determine which product and mechanical modifications will enhance tabletability. Our experts test the proposed modifications and suggest actions, such as blending or granulation to further improve tabletability of your

product. We'll help you identify the correct excipients to use based on your API's behavior. Natoli Scientific will also test product flow and particle size distribution to determine whether dry or wet granulation is required.

### Our testing provides:

- Tabletability and compactibility profiles
- Compaction simulation data (e.g. Heckel plots, work curves)
- Ejection profiles to optimize powdered lubrication

...and more!

## Let us assist you in your challenges with:

### FORMULATION

- » Material characterization
- » Formulation design
- » Release profiles – immediate, extended, etc.
- » Powder flow

### GRANULATION

- » Particle size
- » Friability
- » Sticking
- » Processability
- » Agglomeration

### MILLING

- » Particle size distribution
- » Blade and screen type selection
- » Extrusion

### HOT MELT EXTRUSION

- » Polymer selection
- » Crystallinity (vs. amorphous)

### TABLETING

- » Sticking/picking
- » Capping/lamination
- » Discoloration
- » Scalability

### COATING

- » Twinning
- » Spray drying
- » Orange peeling
- » Color uniformity

### BLENDING

- » Order of addition
- » Lubrication times
- » Uniformity studies



# SCALE-UP SUPPORT

The transition from development to full-scale production can lead to unwanted surprises. Natoli Scientific's laboratory capabilities provide detailed powder characterization studies and scale-up assistance using limited quantities of material. Our Telford, Pennsylvania laboratory features a fully instrumented **Presster Compaction Simulator** that can test single tablets using less than one gram of API.

Our experts will determine how your formulation will perform during full-scale production by running tests on the Natoli NP-RD30 rotary tablet press. This innovative press will match the dwell times, turret speed, and vertical punch velocities of your production press.

### Our scale-up support provides:

- Formulation modification to improve tablet quality
- Tabletability and compactibility profiles
- Measurements for compression cycles: dwell time, turret velocity, vertical punch velocity, etc.
- Containment/Clean-up protocol creation
- Your formulation's character material deformation properties
- A library of data that allows simulation of production speeds for most brands of tablet press
- On-site consulting services



Natoli's NP-RD30 replicates the design and functionality of a full-scale production press.



The Presster can test a single tablet at production speed from a library of press models.

## TABLET DESIGN RECOMMENDATIONS

Natoli Scientific experts can recommend an efficient and effective tablet design for your product based on your formulation's characteristics and your manufacturing requirements and restrictions.

## TOOL MATERIAL & COATING RECOMMENDATIONS

The proper tool steel type, tool coating, and die configurations are critical to successful tableting, particularly for difficult formulations. Natoli Scientific will recommend tooling materials to support your product and keep production running smoothly.

# TABLET PRESS CALIBRATION & PREVENTIVE MAINTENANCE

Scheduled calibration and preventive maintenance of your tablet press can reduce tablet defects and increase productivity. Our experienced technicians provide on-site system calibration, calibration verification, and preventive maintenance services to protect your investment by keeping your tablet compression equipment in optimal operating condition.

## SYSTEM CALIBRATION

A complete system calibration includes adjusting your instrumentation monitoring system to reflect the results of the calibration. All standards are NIST traceable and calibrated within the preceding 12 months to ensure accuracy. A signed Certificate of Calibration is provided for each calibrated sensor.

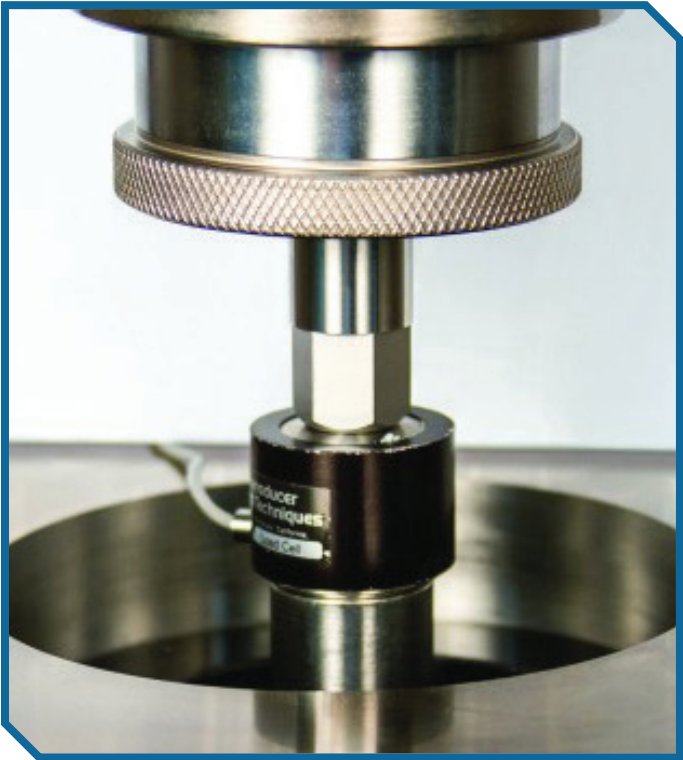
## CALIBRATION VERIFICATION

We verify the sensor readings on your equipment by comparing them to our calibrated standards. The Natoli calibration verification service also provides a detailed report/readout of the sensitivity value of your sensors, allowing you to compare your current settings and determine whether your software needs to be updated. Adjustments are not made as part of the calibration verification service.

## PREVENTIVE MAINTENANCE & ASSESSMENTS

Scheduled preventive maintenance can extend the life of your tablet compression equipment as well as enhance performance, improve tablet quality, and increase production yields. We will assess the condition of your equipment and provide you with a written recommendation for regular maintenance procedures.

We recommend calibration at least once a year to maintain tablet quality. These services include calibration of instrumented components to ensure optimal performance along with documentation to meet compliance requirements.



Force calibration testing on a single-station tablet press.

### Our expert technicians will check for:

- » Visual damage
- » Die table run-out
- » Upper/lower punch guide wear
- » Cam condition and wear
- » Pressure roll and pin conditions
- » Die pocket wear

# R&D ANALYTICAL AND PRODUCTION CONTROL SOFTWARE

## FOR R&D TABLE PRESSES

Natoli Scientific can retrofit your current R&D press with **Natoli AIM™ Data Acquisition and Analytical Software** to enhance and simplify your R&D processes. Our industry-leading software combines tableting data imported from your press and manually entered tablet parameters to automatically generate plots for tableability, compactibility, compressibility profiles and more that goes straight into Microsoft Excel.

If your current press already has analytical software, our experts can customize an upgrade to include the advanced features and benefits of **Natoli AIM™ Data Acquisition and Analytical Software**.

## FOR PRODUCTION TABLE PRESSES

Enhance the performance of an outdated production press with **Natoli AIM™ ProPlus Custom** control system. Tailored to your specific requirements, **Natoli AIM™ ProPlus Custom** control systems are designed to:

- » Improve ease of operation of your existing tablet press
- » Increase tablet production
- » Report 21 CFR Part 11-compliant data
- » Reduce product loss
- » Improve tablet quality
- » Reduce tableting costs

The **Natoli AIM™ ProPlus Custom** control system is network-ready with secure datasets that meet the **FDA's** electronic records requirements. Report generation and storage are easy, and batch reports can be transferred to secure network drives for shared views, data backup, and secure storage. Press operators can easily and quickly generate:

- » Activity/performance reports
- » Product and variation reports (RSD)
- » Batch and end-of-batch reports
- » Error code and alarm reports
- » Audit trail of changes during batch production



Single-station R&D press with data acquisition and analytical software.



Reconditioned Kikusui press with enhanced control system.

Calibration verification and preventive maintenance available for all press models. System calibration available for select models only.



# HANDS-ON TECHNICAL TRAINING

Natoli Scientific's regularly scheduled and customized training courses provide comprehensive insight into tablet development, scale-up, manufacturing, and more within a unique classroom setting and through hands-on experiences. Our technical training incorporates expert panel discussions, problem-solving exercises, live demonstrations, one-on-one consultations, open peer discussions, and Q&A.

Training instructors include Natoli technical experts and other industry thought leaders who share their knowledge directly with you. Attendees can present

their challenges not only to the instructors, but also to their peers who may have encountered similar problems and developed unique solutions.

Our training courses enable you to see the real-world applications of the lectures and participate in the process. Subject matter experts share their experience on topics like tablet coating and dry granulation, and attendees can use what they learned in hands-on laboratory exercises.



## LEARN

new approaches to  
formulation development



## BUILD

relationships for lasting support with  
industry experts and peers



## ENHANCE

critical thinking and  
problem-solving skills



## APPLY

scientific principles to your own  
formulation development

# KNOWLEDGE & EXPERIENCE SHARING

## WHO SHOULD ATTEND?

Our training events are designed for those involved in tableting R&D including:

- » Compounding pharmacists
- » Formulation scientists
- » Research associates
- » Technology transfer scientists
- » Process and validation engineers
- » R & D Directors
- » Technical Project and Product Managers
- » Manufacturing Supervisors

## LEARNING OBJECTIVES

Attendees will obtain a greater understanding of the following topics:

- » Formulation development strategies
- » Excipient selection
- » Blending
- » Powder rheology
- » Compaction emulation
- » Tablet design
- » Granulation (roller compression, high shear, fluid bed)
- » Tablet compression with scale-up
- » Tablet coating

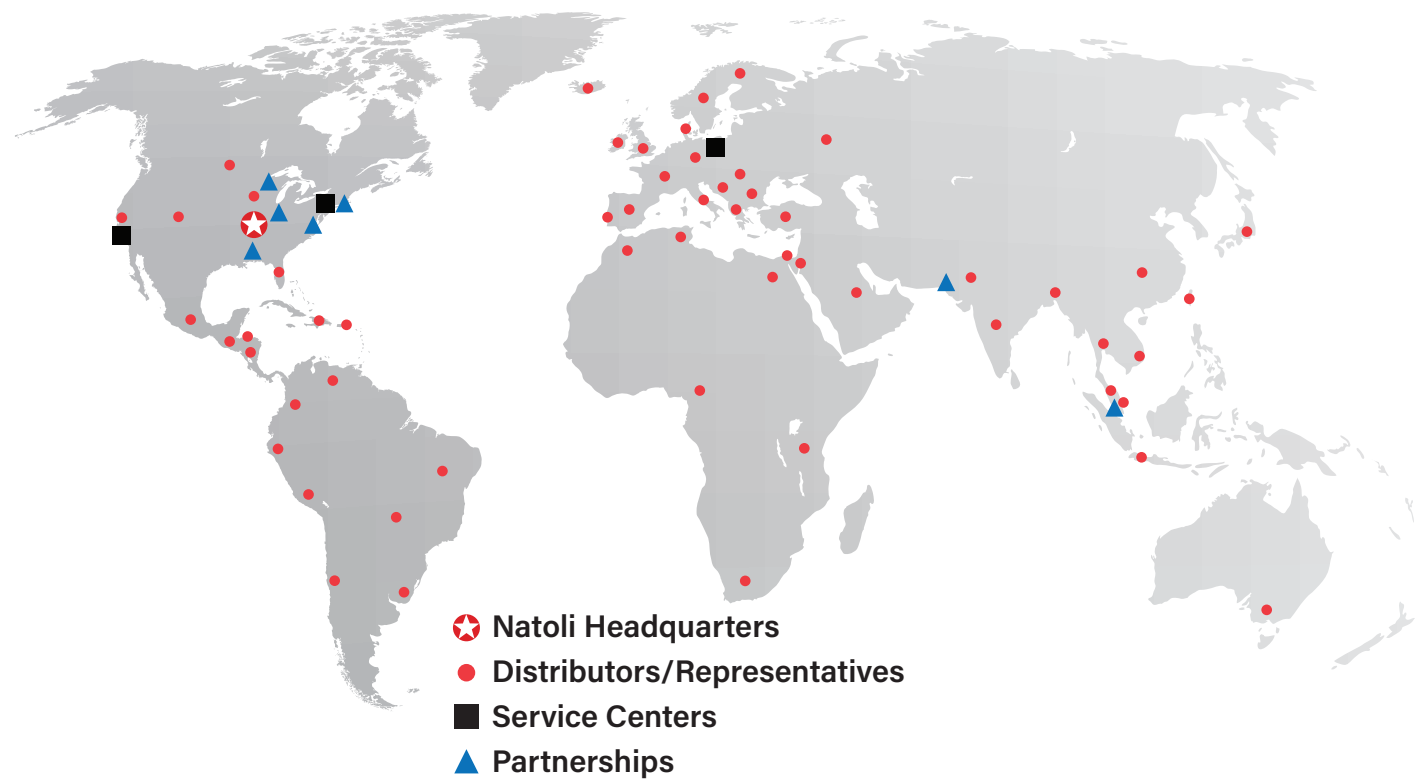
Check **Natoli.com/training-event-calendar**  
for upcoming training dates or customized  
on-site training availability!





# WORLDWIDE SUPPORT

Benefits Customers & Industry



With laboratory facilities in Missouri and Pennsylvania, and support from our partnerships, regional representatives, and service centers, Natoli Scientific has the resources to assist you worldwide.

## INVESTING IN EDUCATION

for the future of developments in pharmaceutical manufacturing

Natoli Engineering supports education and values its partnerships with universities as they propel advancements in tablet compression and continuous manufacturing. Natoli's support gives students hands-on experience while they work to establish industry best practices and prepare for their future careers.

Natoli is an active member of C-SOPS (Center for Structured Organic Particulate Systems), which allows industry leaders and universities to work together to improve the pharmaceutical manufacturing process. By collaborating with the next generation of tablet compression experts, Natoli can continue to drive innovations in tableting.

## LET NATOLI SCIENTIFIC WORK FOR YOU.



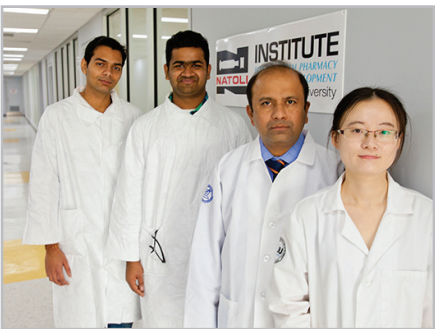
Natoli R&D Laboratory | Telford, PA

Our state-of-the-art R&D laboratory in Telford, Pennsylvania houses a full range of bench-top R&D and production tablet presses, dry and wet granulation machines, a compaction emulator, and coating equipment. The troubleshooting and custom research services we perform address each stage of product development.



Natoli Technical Training Center | St. Charles, MO

The St. Charles facility offers classroom and hands-on tablet manufacturing process training. Natoli Scientific classes help those involved with R&D learn about granulation principles and best practices; common excipients and their designed functions; factors that can influence successful tablet coating; and the importance of characterization, measurement, blending, and more.



### NATOLI INSTITUTE AT LONG ISLAND UNIVERSITY

The Natoli Institute of Industrial Pharmacy Research & Development is a partnership between Natoli Engineering and The Arnold and Marie Schwartz College of Pharmacy and Health Sciences at Long Island University.

The institute supports one of the few industrial pharmacy programs in North America and offers graduate students the opportunity to find innovative solutions to complex formulation challenges through research implementation.



### NATOLI TABLET COMPRESSION LAB AT THE UNIVERSITY OF KARACHI

The Natoli Tablet Compression Lab in the Department of Pharmaceutics at the University of Karachi helps prepare students for their careers in tablet compression. Natoli has equipped the lab with an NP-RD10A single-station R&D tablet press. The University of Karachi is one of the most respected institutions in Pakistan, and many who work in Pakistan's pharmaceutical industry are graduates of the university.

## NATOLI ENGINEERING: Dedicated to Supporting Our Industry

Natoli Engineering Company is the world-renowned leader in tablet press tooling manufacturing. **But we are far more.** Founded on the uncompromising principle to manufacture and deliver the highest quality products at a fair price with exceptional customer service, Natoli continues to build on over 45 years of innovation and industry leadership.

### NATOLI ENGINEERING PROVIDES UNPARALLELED SUPPORT IN:



Tool Design



Tablet  
Compression  
Accessories



Technical Training



Tablet Design



Tablet Press  
Replacement Parts



Regional Service  
Centers



Tablet Press  
Refurbishment



Scientific and  
On-Site Consulting



Encapsulation



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