

Pharmasolutions

A Comprehensive Drug Development
and Testing Service

www.spipharma.com



Serious Equipment for Serious Work

Pharmasolutions

Pharmasolutions is a comprehensive drug development and testing service available from SPI Pharma. Unlike a CRO, we are an ingredients manufacturer with materials and functionality expertise. Expand your product's life cycle possibilities. Reduce trial and error. Get to market faster.

SPI Pharma houses a full-fledged development lab with capabilities including:

HPLC/UPLC	Roller compactor	Dissolution USP II
Soft Gel	Instrumented tablet press	Disintegration Apparatus
Blister packaging	Bottle packer	ICH chambers and instrumentation to assess the physical properties of solid dosage forms
Spray dryer	Stick pack/sachet packer	
High shear granulator	DSC	

How It Works

Pharmasolutions is a fee for service business model. We set mutually agreeable milestones based on QbD process and you pay for the successful completion of those milestones. The plan is flexible. You can choose parts of the solution or a complete package- whatever **makes a difference** for your team.



Why Outsource Your Drug Development Project?

SPI Pharma houses a full-fledged development lab with capabilities including:

SPI Pharma combines our proprietary excipients with your API to create your new product. We offer complete solutions through versatile and cost effective options for your generic, NCE, nutraceutical and OTC products. We specialize in unique and oral dispersible dosage forms. Our patient friendly dosage platforms include a line of taste masked actives.

Track Record

We have developed a database that reduces trial and error to bring your product to market faster. Examples are available in the Pharmasolutions sell sheet. Your success is our focus.



Experience and Talent

Our development lab features a team of pharmaceutical scientists with over 95 years of combined formulation experience from big pharma as well as mid-size branded and generic labs. The team is dedicated to formulation development, application research, analytical development and analytical validations (non-GMP).



Excipients for Swallow Tablets



Taste Masked Actives



ODTs/ODPs



Effervescent Tablets



Vaccine Adjuvants



Soft Gel Capsules



Antacid & Laxative Ingredients



Chewable Tablets & Lozenges



Nutraceutical Applications

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Pharmasolutions

SPI provides our know-how and laboratory capabilities to assist your development on a fee for service basis. SPI acknowledges that manufacturing in your equipment may yield different results. Choose from the list below, or collaborate with us on your next innovation!


Active Ingredients	API	Dosage Form	Strengths	Tablet Weights	Excipients	Stability Data	Reference Product	Comparison Data	License Available	
Tadalafil	Base Ph. Eur	ODT	20mg	200mg	Pharmaburst® 500 Lubripharm® SSF	N/A	Cialis®	Dissolution Similarity Rate	Worldwide except MENA ³	
Ondansetron	Base USP	ODT	4mg 8mg	150mg 300mg	Pharmaburst® C1 Lubripharm® SSF	40/75 - 3 mos	Zofran ODT®	Dissolution Similarity Factor	Worldwide	
Carbidopa/ Levodopa	Both USP	ODT	10/100mg 25/100mg 25/250mg	399mg 398mg 998mg	Pharmaburst® C1 Lubripharm® SSF Mannogem® Mannitol	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	Parcopa	Dissolution Similarity Factor	Worldwide except US, Canada, Mexico	
Rizatriptan	Benzoate USP	ODT	5mg 10mg	150mg 300mg	Pharmaburst® C1	40/75 - 3 mos	Maxalt-MLT®	Dissolution Similarity Factor	worldwide except US, Canada, Mexico	
Acetaminophen	Taste masked IH	ODT	250mg 160mg 125mg 80mg	900mg 576mg 450mg 288mg	Pharmaburst® 500 Lubripharm® SSF Actimask® Acetaminophen	25/60 - 12 mos 30/65 - 12 mos 40/75 - 6 mos	Tylenol®	Dissolution Similarity Factor	Worldwide	
Nicotine ¹	Nicotine Polacrilex USP	Lozenge	2mg 4mg	1200mg 1200mg	Mannogem® NL Effer-Soda® 12 Lubripharm® SSF	25/60 - 12 mos 40/75 - 6 mos	Commit® Lozenge	Dissolution Similarity Factor	Worldwide except US, Canada, Mexico, EPO ²	
Loratadine	Base	ODT	5mg 10mg	150mg 300mg	Pharmaburst® C1	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	Claritin® Reditab®	Dissolution Similarity Factor	Worldwide	
Phloroglucinol	Dihydrate Ph. Eur	ODT	80mg	400mg	Pharmaburst® B1	25/60 - 3 mos 30/65 - 3 mos 40/75 - 3 mos	Spasfon Lyoc	Dissolution Rate	Worldwide	
Domperidone	Ph. Eur	ODT	10mg	300mg	Pharmaburst® B1 Lubripharm® SSF	25/60 - 6 mos 30/65 - 6 mos 40/75 - 6 mos	Motilyo® Lyophilisat	Dissolution Rate	Worldwide	
Mirtazapine	USP	ODT	15mg	300mg	Pharmaburst® C1 Lubripharm® SSF	25/60 - 3 mos 30/65 - 3 mos 40/75 - 3 mos	Remeron SolTab	Dissolution Rate	Worldwide	
Risperidone	Benzoate	ODT	2mg	500mg	Pharmaburst® B1 Lubripharm® SSF	25/60 - 3 mos 40/75 - 3 mos	Resperdal® M-tab®	Dissolution Rate	Worldwide	
Loperamide	HCl USP/ EP	ODT	2mg	200mg	Pharmaburst® B1	25/60 - 3 mos 30/65 - 3 mos 40/75 - 3 mos	Imodium® Capsule (Europe)	Imodium® Quick Dissolve (Canada)	Dissolution Similarity Factor	Worldwide except Europe ⁴

- 1 Data package includes pilot PK study data and information for facilitating development of a commercial ODT product.
- 2 European Patent Organization as of July 2012: Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, Turkey.
- 3 MENA Territory: Kingdom of Saudi Arabia, Kuwait, Qatar, Bahrain, UAE, Oman, Iraq, Jordan, Lebanon, Palestine, Egypt, Libya, Tunisia, Algeria and Morocco.
- 4 European Union as of Dec 2006: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom




Pharmasolutions

Drug Development Service




Innovative




Specializing in
Patient Friendly Dosage Forms

Experience



- ➔ **Material & Formulation Expertise**
- ➔ **Skilled Development Scientists in US & India**
- ➔ **Track Record of Success**

Possibilities



- ✔ **Extend Lifecycle**
- ✔ **Reduce Trial & Error**
- ✔ **Speed Development**

Get to Market Faster

Simple

Flexible

Pay for Success

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