



Pharmasolutions

Let's Customize Your Next Drug



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.

Why Outsource Your Drug Development Project?

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

Based on the track record below, we have developed a database that reduces trial and error to bring your product to market faster. Your success is our focus.

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

1 Data package includes pilot PK study data.

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.

Serious Equipment for Serious Work

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


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

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).


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 works best for your team.




Pharmasolutions

Drug Development & Testing Service





Product Life Cycle Management





Drug Development Capabilities

Formulation Development & Optimization

-  Taste-Masking
- ICH Stability & Product Prototypes
- Analytical Method Development/Validation

Manufacturing Scale-Up & Support

-  Clinical Studies Through CROs
-  Full Dossier in CTD Format Ready for Registration

Simple

Flexible

Pay for Success

Let's customize your next drug.

Contact SPI Pharma today for more information: salesinfo@spipharma.com or www.spipharma.com

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