

A Trusted Partner for Pharmaceutical Industry Leaders

Corporate Presentation



An Independent API Company You Can Trust



A world-class developer and manufacturer of differentiated **Active Pharmaceutical Ingredients**



Global Presence - More than **280 customers** in over **50 countries**



Customer oriented – We are on the **same wavelength**, always in tune with the results required to support your needs



More than 30 years of exceptional regulatory track record with leading global regulatory authorities (USFDA, EU-EMA, PMDA, TGA, KFDA, ANVISA and COFEPRIS)



Scale – Producing more than **630 metric tons** every year



Strong expertise in complex chemistry, process optimization and scale up, crystalline forms and particle design



An Independent API Company You Can Trust



Leading R&D capabilities and strong regulatory expertise **200 DMFs worldwide**



Full range of **API CDMO** services from **pre-clinical grams** to **multi ton commercial scale**



Back-integration capabilities - key regulatory starting materials and advanced drug intermediates for complete **supply chain assurance**



Customized solutions to meet individual customer requirements



Creative business models to get to market, including co-development partnerships



Long heritage of excellence, and **global leadership** in select molecules



Over 30 Years of Exceptional Service

























New Ownership – Renewed Focus

SK CAPITAL

- A New York based transformational private investment firm with a disciplined focus on the pharmaceuticals and specialty chemicals sectors
- The firm's \$5.5B portfolio includes 20 companies generating aggregate annual revenues of \$11B, employing +15,000 people globally, with 126 plants operating across 28 countries and selling to customers in 115 countries









- Vast industry and operating experience, augmenting leadership teams with strong talent to transform businesses into higher performing standalone customer-centric organizations
- Building strong and growing businesses that create substantial **long-term value** with improved strategic positioning as well as lower operating risk



Leadership Team



CEOIftach Seri



VP SalesFrédéric Kahn



Chairman of the Board

Aaron Davenport



VP BD Marketing & IP



VP R&D

Benzion Dolitzky



Director Itzhak Krinsky



DirectorBarry Penney



CFOTami Cohen



VP Quality, RA & Compliance
Sarah Isaacs



DirectorMeron Mann



DirectorStephen d'Incelli



Head of HR
Liat Mayan



Head of Operations

Amit Kalimi



DirectorArik Yaari



Working with Us is Always an Advantage wavelength wavelength

Committed to Quality

- Strict compliance with the most stringent cGMP standards of all key global regulatory bodies
- Highly experienced team of over 120 quality assurance and quality control personnel
- Consistent supply of high-quality APIs since 1987
- Over 100 successful customer and health authorities audits in the past 5 years
- Israeli MoH audit in February 2019 mutually recognized by the EU as EU GMP (no observations)
- USFDA audit in July 2018 (no 483s)



















Wavelength Pharmaceuticals - A Partner You Can Trust





















































Global Presence - 280 customers in 50 countries

>80% of sales in US, EU & Japan



Reliable Supply of Essential Drugs - COVID19



Over 30 years of investment in building a **Robust Supply Chain** and an impeccable **Regulatory Track Record** have enabled us to quickly respond to the urgent need for life-saving care for critically ill COVID-19 patients.



Meticulous **Process Design** has supported rapid and **Right-First-Time** x3-x4 scale up of **Midazolam**, **Cisatracurium Besylate** and **Rocuronium Bromide** production in response to massively increased demand.



Iftach Seri, CEO of Wavelength Pharmaceuticals: "Our commitment to being 'Always Aligned' with the needs of our customers drove us to invest in the required capabilities and expertise that now allow us to respond so quickly to the urgent global need of respiratory critical care drugs for COVID-19 patients."



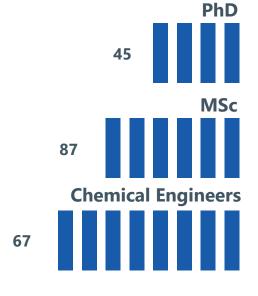
API Custom Development and Manufacturing Services

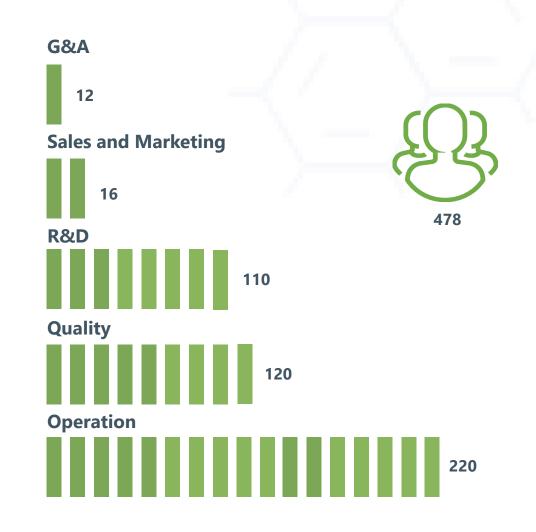
- Technology Transfer
- Process Development and Optimization
- Enzymatic Process Development
- Analytical Methods Development
- Synthesis of Impurities and Standards
- Potential Genotoxic Impurities Evaluation including High Sensitivity Analytical Methods
- Solid State (Polymorphism screening / Salts / Co-Crystals)
- Characterization of Physical Properties
- Particle Design
- Spray Drying & Bioavailability Enhancing
- Scale Up, Process & Analytical Methods Validation
- cGMP Manufacturing Grams to Multi Ton Scale
- APIs, Advanced Drug Intermediates and Key Starting Materials



People Are Key To Our Success









Leading R&D Capabilities and Strong Regulatory Expertise



110 R&D scientists and 10 regulatory experts, 4 R&D sites in Israel and India



Quality by Design and complete regulatory support throughout the product lifecycle



Extensive knowhow and experience in filing Drug Master Files with many different agencies, enables us to provide

Best-in-Class Global Regulatory Support



United States 34 USDMF

Europe 30 EDMF 15 CEP

Japan 11 JDMF

Korea 7 KDMF

Rest of World 103

Total 200 DMFs



World-Class Manufacturing Facilities



Wide range of multi-purpose production capabilities from **preclinical grams to multi-ton commercial scale**



Total reaction volume of 155m³

84 reactors ranging 10L-12,000L including Stainless Steel, Glass-Lined, Hastelloy and **High Pressure Hydrogenators** up to 50bar



Complex chemical reactions including Enzymatic reactions, Heterocyclic synthesis, Brominations, Nitrations and Sulphonations, Cryogenic reactions (-70°C to -85°C), advanced pharmaceutical technologies including, Lyophilization, Micronization, Particle Design and other Bioavailability Enhancing technologies.



Highly potent compounds, **Steroids** and **Cytotoxics** manufacturing capabilities complying with the strictest containment requirements (OEL <1µg/m³)



Licensed to handle **Highly Controlled Substances**



Ability to **quickly and efficiently Accommodate Customers Growth** translates into lower risk and faster turnaround, all with unparalleled quality, regulatory compliance and exceptional customer service



Environmental and Social Responsibility

- Committed to the highest Environment Protection, Health and Safety standards
- Implementing Best Available EHS Technologies across all fields of operation







 Participating in multiple voluntary community programs with focus on education and health





End to End Drug Substance Solutions



Process Development and Optimization

From Pre-clinical Grams
To Multi-ton
Commercial Scale
Production



Experts in Complex Scale-Ups

Quality By Design Extensive Knowhow And Experience - Right First-Time Approach



Innovation

Enzymatic Processes, Continuous Flow Chemistry, Oligonucleotides, ...



Advanced Technologies

Particle Design,
Micronization,
Polymorphs, Co-Crystals,
Alt Salts, Spray Drying,
Bioavailability Enhancing,
Lyophilization, ...



Wide Range of Capabilities

Inhalables, Injectables, High Potency, Steroids, Cytotoxics, Controlled Substances, ...



Bioavailability & Solubility Enhancement - Spray Drying

- Development and scale up of unique **Spray Drying** solutions
- Enhanced material Solubility and Bioavailability
- Option to add excipients
- Improved chemical and physical stability properties

Scale up capabilities - Pre-Clinical Grams to Commercial Scale

- 2 Lab Spray Dryers BUCHI- B-290
- Small scale Spray Dryer GEA Niro 2kg/h
- Small scale Spray Dryer CPS 6kg/h
- Mid scale Spray Dryer GEA Niro 15kg/h

Experience

- Rocuronium Bromide Amorphous
- Ibrutinib Amorphous
- Imatinib Amorphous
- Donepezil Hydrochloride Amorphous in Lactose
- Montelukast Amorphous



Biocatalytic Process Development



Development and scale up of Enzymatic / Biocatalytic Processes



Advantages

- Greater Enantio / Regio / Stereo Selectivity
- Higher Atom Utilization / Yield
- Overcomes Hazardous Chemical Reactions
- Improved Eco Efficiency
- Fewer Synthetic Steps
- Green Chemistry
- Reduced Waste / Consumption Of Organic Solvents



Experience

- Sitagliptin HCl
- Sitagliptin Phosphate
- Remimazolam Besylate
- Clascoterone
- Cannabidiol



Solid State & Particle Design



Polymorph Screening / Development

Alternate Salts

Co-Crystals



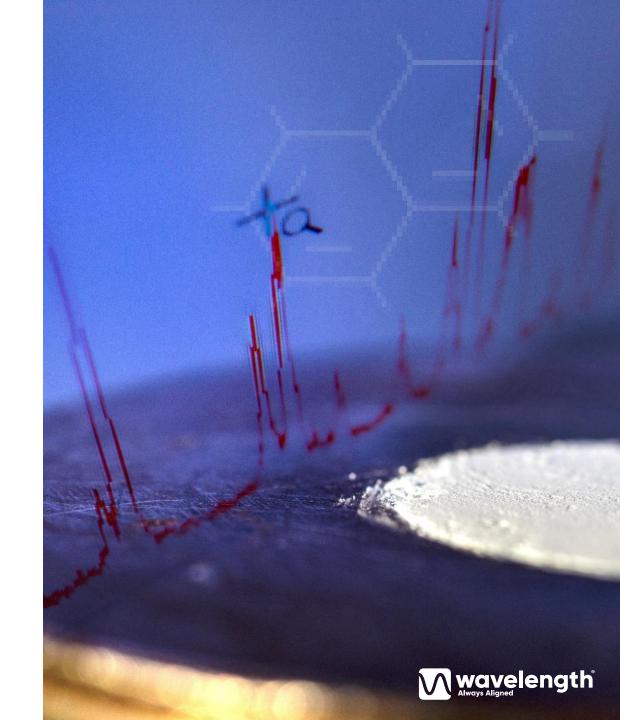
Particle Design

- Morphology
- Particle Size Distribution
- Improved Physico-chemical performance
- Powder flowability



Experience

- Fluticasone Propionate
- Fluticasone Furoate
- Tiotropium Bromide Monohydrate
- Mometasone Furoate
- Halobetasol Propionate
- Cetirizine Hydrochloride Micronized
- Fenofibrate
- Glycopyrronium Bromide
- Umeclidinium Bromide



Solid State & Particle Design



Crystallization Process Design



Wide Range Of Milling And Micronization Equipment

From 5mm To $<5\mu m$ in a single pass

Ultra Low Energy Technology - Minimum Mechanical / Heat Impact

No Impact on Crystalline Properties / No Increase In Amorphous Content



Wide Range of Advanced Analytical Instruments

Thermogravimetric Analysis (TGA)

Differential Scanning Calorimetry (DSC)

Raman spectroscopy

Hot stage microscopy

Scanning Electronic Microscope

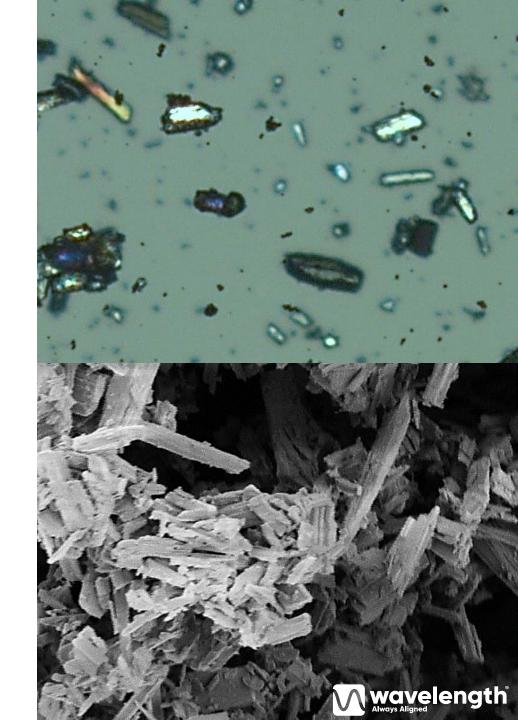
Malvern Particle Size Analysis

Sympatec Particle Size Analysis

X Ray Powder Diffraction (XRPD)

Surface Area

Amorphous Content



Highly Sensitive Analytical Method Development

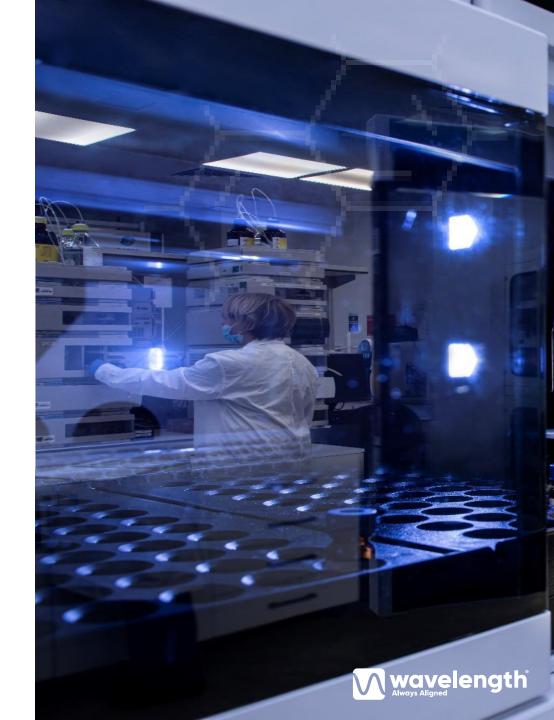


Quantification of **Nitrosamine** and other **Potential Genotoxic Impurities**Highly Sensitive Methods Developed - **Detection Limit 0.03ppm**



Wide Range of **Advance Analytical Instruments**

UHPLC, GC MS, LC MS, FT IR, UV Spectrophotometers, Titrators ...



High Potency APIs

More Than 20 Years of Extensive Experience In Highly Potent APIs

- Development
- Scale-up
- Commercial Production

	OEB4 1 <oel<10 mcg="" m³<="" th=""><th>OEB5 OEL<1 mcg/m³</th></oel<10>	OEB5 OEL<1 mcg/m ³
Cantharidin		
Fluticasone Furoate		
Fluticasone Propionate		
Fulvestrant		
Halobetasol Propionate		
Moxonidine	②	
Rocuronium Bromide		
Temozolomide		
Tiotropium Bromide		
Umeclidinium Bromide		





Wavelength Pharmaceuticals Neot Hovav API Site





12km from Be'er Sheva 1.5hr Drive from Tel Aviv



IL ASH Sea Port 100km TLV Int'l Airport 115km



Total Area 40,700m²
Built 14,000m²

- 1. Main Entrance Gate
- 2. Large Scale Plant 31
- **3.** Large Scale Plant 37
- 4. Mid Scale Plant 720
- **5.** HPAPI Plants 41, 45
- **6.** Pilot Plant 75
- **7.** Pilot Plant 76, 78+R&D Labs
- 8. Utilities Plant
- 9. Effluent Bio Treatment Plant
- 10. Thermal Oxidizer
- 11. Raw Materials Warehouse
- **12.** Final Product Warehouse
- **13.** QC labs & Admin Offices
- **14.** R&D Labs
- **15.** Available for Expansion
- **16.** Scrap Yard / Available for Expansion



Vanamali Organics Hyderabad DI & KSM Sites



Vanamali Organics Pvt. Ltd.

Unit-I Plots No. 24A & 24B

Unit-II Plot No. 32

IDA Mankhal, Maheswaram (M), Ranga Reddy District, Telangana, India



3.75km from Hyderabad



Hyderabad Airport 6.2km Railway Station 20km



Total Area 9,790m²
Built 3,360m²



Vanamali Organics Pvt. Ltd.

Plots No. 117 & 126, IDA Phase-II, Pashamailaram, Patancheru (M), Sangareddy District, Telangana, India



1hr Drive from Hyderabad

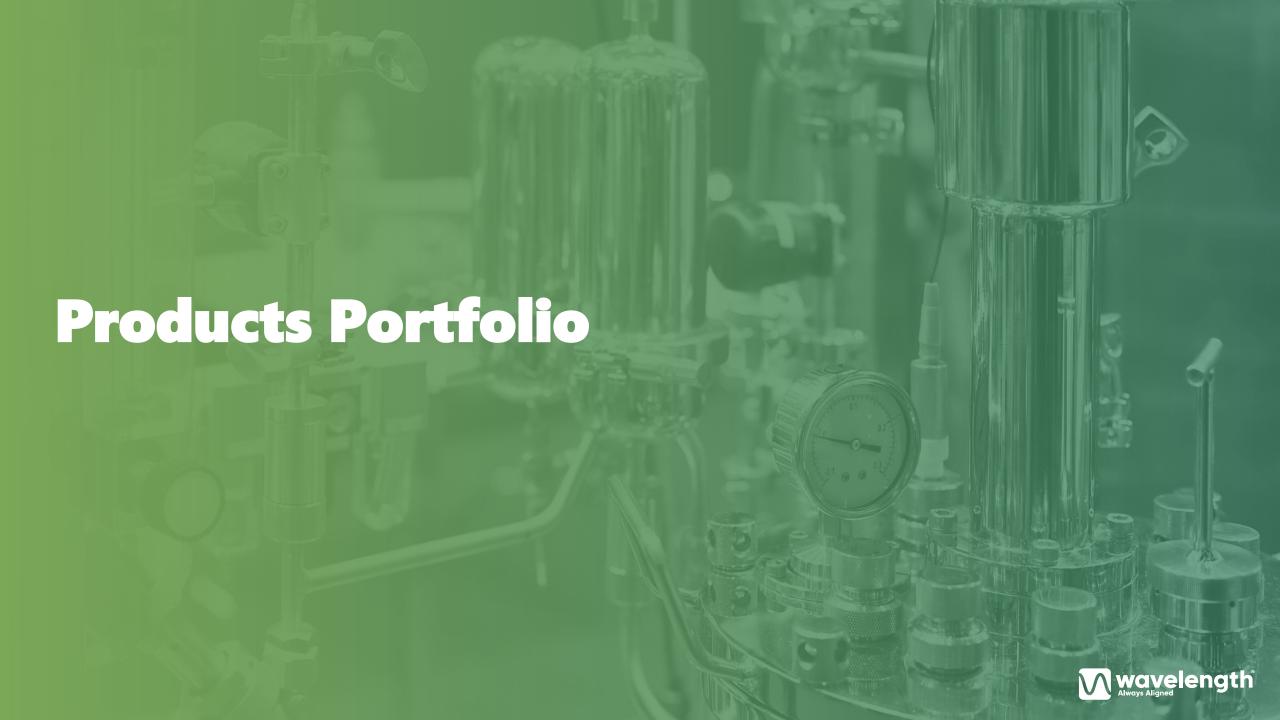


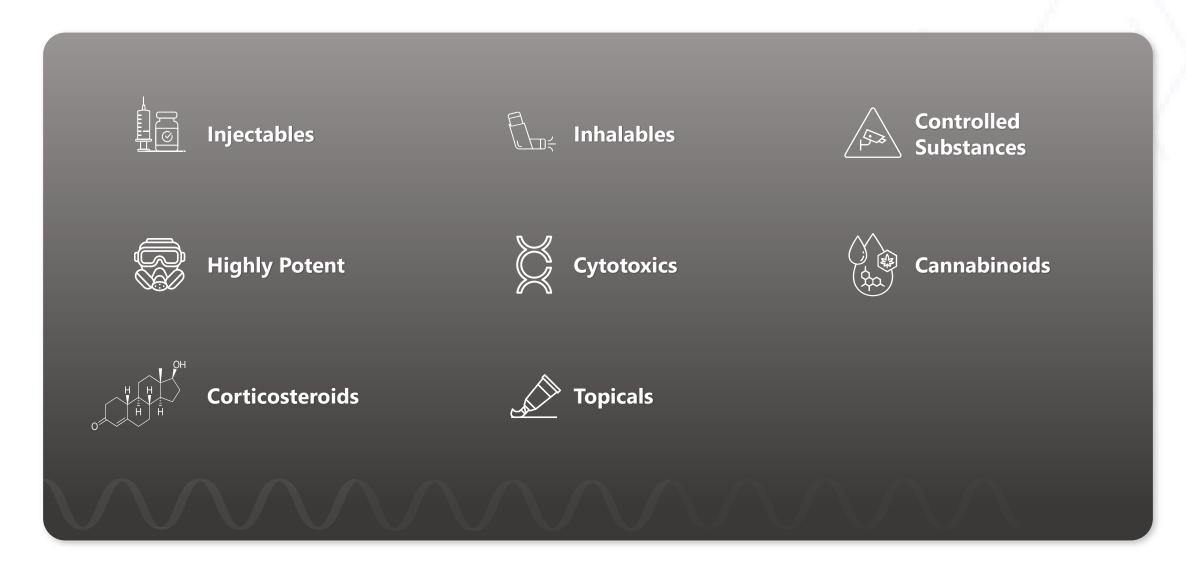
Shamshabad Airport 40km Railway Station 15km



Total Area 2,264m² Built 860m²









Under Development

API	Therapeutic Use
Cannabidiol	Seizures
Cantharidin	Molluscum Contagiosum
Clascoterone	Acne, Alopecia
Remimazolam	Sedation, Amnesia, Anesthesia
Sitagliptin HCl / Phosphate	Type II Diabetes
Umeclidinium Bromide	Chronic obstructive pulmonary disease (COPD)

Under Evaluation

API	Therapeutic Use
Glycopyrronium Bromide	Chronic obstructive pulmonary disease (COPD)
Melphalan Flufenamide	Multiple Myeloma
Plinabulin	Chemotherapy Induced Neutropenia
Relugolix	Uterine Fibroids, Prostate Cancer
Ruxolitinib Phosphate	Myelofibrosis, Polycythaemia vera, Graft-versus-host disease
Tirbanibulin	Actinic keratosis
Vilanterol Trifenatate	Chronic obstructive pulmonary disease (COPD)





New Products

API	Therapeutic Use	Available DMFs
Efinaconazole	Onychomycosis of the toenail or fingernail	USDMF
Fluticasone Furoate	Seasonal and perennial allergic rhinitis, COPD	USDMF
Ibrutinib	Mantle cell lymphoma, Chronic lymphocytic leukemia	USDMF
Pralidoxime Chloride	Treatment of Organophosphates Poisoning	USDMF
Rotigotine	Parkinson's disease	USDMF
Sugammadex	Antidote for Vecuronium and Rocuronium	USDMF
Tavaborole	Onychomycosis of the toenail or fingernail	USDMF
Tiotropium Br Monohydrate	COPD	USDMF, CEP, CDMF

Commercial Products

API	Therapeutic Use	Available DMFs
Ammonium Lactate	Ichthyosis and Xerosis	USDMF
Anastrozole	Breast cancer	CEP, KDMF
Cetirizine Dihydrochloride	Seasonal and perennial allergic rhinitis	USDMF, CEP, JDMF, CADMF
Cilostazol	Intermittent claudication	USDMF, JDMF, KDMF, BRDMF
Cisatracurium Besylate	Neuromuscular blocking agent	USDMF, CEP, CADMF, BRDMF, AUDMF
Donepezil Base	Alzheimer's-type dementia	USDMF, CEP, KDMF
Donepezil Hydrochloride	Alzheimer's-type dementia	USDMF, CEP, JDMF



Commercial Products (continued)

API	Therapeutic Use	Available DMFs
Fenofibrate	Hyperlipidemia; Hypertriglyceridemia	USDMF, CEP, CADMF
Fexofenadine Hydrochloride	Allergy symptoms	USDMF
Flumazenil	Reversal of sedative effects of benzodiazepines	USDMF, CEP, JDMF, KDMF, CADMF, BRDMF, AUDMF
Fluticasone Propionate	Asthma, COPD	USDMF, CEP, JDMF, KDMF, CADMF, BRDMF
Fulvestrant	Breast Cancer	USDMF, CEP
Granisetron Base	Chemotherapy-induced nausea and vomiting	USDMF
Granisetron Hydrochloride	Chemotherapy-induced nausea and vomiting	USDMF, CEP, JDMF, KDMF, CADMF
Halobetasol Propionate	Topical anti-inflammatory and antipruritic conditions	USDMF
Imiquimod	Actinic keratoses (AK); Superficial basal cell carcinoma; Genital and perianal warts/condyloma	USDMF
Midazolam	Sedation; Amnesia; Anesthesia	USDMF, CEP, JDMF, KDMF, CADMF, BRDMF, AUDMF
Modafinil	Narcolepsy, obstructive sleep apnea, and shift work disorder	USDMF, CEP, BRDMF, AUDMF
Mometasone Fur. Anhydrous	Asthma	USDMF



Commercial Products (continued)

API	Therapeutic Use	Available DMFs
Mometasone Furoate Monohydrate	Allergic Rhinitis	USDMF, EDMF, CADMF, BRDMF, CDMF
Moxonidine	Hypertension	CEP
Omeprazole Magnesium	Duodenal and gastric ulcer; Gastroesophageal reflux disease	USDMF
Palonosetron Hydrochloride	Chemotherapy-induced nausea and vomiting; Post-operative nausea and vomiting	USDMF, EDMF, JDMF
Permethrin	Treatment for scabies	USDMF, CEP
Pramipexole Dihydrochloride	Parkinson's disease	USDMF, BRDMF
Rocuronium Bromide	Adjunct to general anesthesia	USDMF, KDMF, CADMF
Temozolomide	Glioblastoma multiforme (GBM)	USDMF, EDMF, CADMF, BRDMF
Terbinafine Hydrochloride	Onychomycosis of the toenail or fingernail	JDMF, BRDMF
Tramadol Hydrochloride	Management of moderate to moderately severe pain	USDMF, CEP, JDMF, KDMF, CADMF, BRDMF, AUDMF





Select Advanced Drug Intermediates

API	Intermediate	CAS
	Ethyl-2-amino-1,3-thaizole-4 carboxylate	5398-36-7
Acotiamide	N,N-Diisopropylethylenediamine	121-05-1
	2,4,5-trimethoxybenzoicacid	490-64-2
Bortezomib	(aR,3aS,4S,6S,7aR)-Hexahydro-3a,8,8-trimethyl-alpha-(2-methylpropyl)-4,6-methano-1,3,2-benzodioxaborole-2-methanamine 2,2,2-trifluoroacetate	179324-87-9
Clofazimine	N-(4-Chlorophenyl)-1,2-benzenediamine	68817-71-0
Clozapine	8-Chloro-110xo-10,11-Dihydro-5 H-Dibenzo-1,4-Diazepine	50892-62-1
Donepezil	5,6-Dimethoxy-2-(4-piperidinylmethyl)-1-indanone hydrochloride	120013-39-0
osaprepitant	Tetrabenzyl diphosphate	990-91-0
Gadobutrol	1,2,4-butanetriol-3-(1,4,7,10-tetraazacyclododec-1-yl)4hydrochloride	156077-56-4
iadobutroi	4,4-dimethyl-3,5,8-trioxabicyclo[5.1.0]octane	57280-22-5
/licafungin	4-{5-[4-(Pentyloxy)phenyl]-1,2-oxazol-3-yl}benzoic acid	179162-55-1
osaconazole	1-(4-Aminophenyl)-4-(4-hydroxyphenyl)piperazine	74853-08-0
	2,3-Dimethyl-6-nitro-2H-indazole	444731-73-1
D '1	2,3-Dimethyl-2H-indazol-6-amine hydrochloride	635702-60-2
Pazopanib	5-Amino-2-methylbenzenesulfonamide	6973-09-7
	2,4-Dichloropyrimidine	3934-20-1
ermethrin	3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarbonyl chloride	52314-67-7
Ractopamine	2-(4-(4-hydroxyphenyl)butan-2-ylamino)-1-(4-hydroxyphenyl)ethanone hydrochloride	52446-58-9
/arenicline	2,3,4,5-Tetrahydro-7,8-dinitro-3-(trifluoroacetyl)-1,5-methano-1H-3-benzazepine	230615-59-5







An Independent API Company



Worldwide Regulatory Expertise with Unparalleled Quality & Compliance Track-Record



Leading R&D Capabilities and Advanced Technologies



Full Range of Back Integrated Manufacturing Capabilities API, KSM, DI from Pre-Clinical Grams to Multi-Ton Commercial Scale



Highly Experienced and Accessible Management Team that Puts customers First



Strategic Account Management with Exceptional Customer Care



Supply Assurance – On Time and In Full



A Partner You Can Trust



