

# Portfolio Drug Substance

List Products	Therapeutic Areas	Monographs	Regulatory Documentation	DEA Schedule	CAS Number	Produced in
Acemetacin	Nonsteroidal anti-inflammatory	Ph. Eur.	CEP	n.a.	53164-05-9	
Aminophylline Anhydrous	Bronchodilator	Ph. Eur., USP	CEP	n.a.	317-34-0	
Aminophylline Hydrous	Bronchodilator	JP, Ph. Eur., USP	CEP	n.a.	5897-66-5	
Amobarbital Sodium	Anticonvulsant, sedative	USP	USDMF	II	64-43-7	
Amylmetacresol (AMC)	Antiseptic agent	Ph. Eur.	CEP	n.a.	1300-94-3	
Articaine HCl	Anesthetic	Ph. Eur., USP	CEP/USDMF	n.a.	23964-57-0	
Benoxinate HCl	Anesthetic	Ph. Eur., USP	ASMF/USDMF	n.a.	5987-82-6	
Benzonatate	Antitussive	USP	USDMF	n.a.	104-31-4	
Bethanechol Chloride	Parasympathomimetic (Cholinergic)	USP	ASMF/USDMF	n.a.	590-63-6	
Bupivacaine Base	Anesthetic	n.a.	ASMF/USDMF	n.a.	38396-39-3	
Bupivacaine HCl	Anesthetic	Ph. Eur., USP	CEP/USDMF	n.a.	14252-80-3	
Buprenorphine Base	Analgesic, opioid addiction	Ph. Eur.	CEP/USDMF	IIIN	52485-79-7	
Buprenorphine HCl	Analgesic, opioid addiction	Ph. Eur., USP	CEP/USDMF	IIIN	53152-21-9	
Butalbital Base	Sedative	USP	USDMF	III	77-26-9	
Caffeine Anhydrous	Stimulant	IP, JP, Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	58-08-2	
Chloroprocaine HCl	Anesthetic	USP	ASMF/USDMF	n.a.	3858-89-7	
Choline Salicylate 80%	Analgesic/Anti-inflammatory	n.a.	ASMF/USDMF	n.a.	2016-36-6	
Cyclizine Base	Antiemetic, Histamine H1 antagonist	n.a.	ASMF	n.a.	82-92-8	
Cyclizine HCl	Antiemetic, Histamine H1 antagonist	n.a.	ASMF	n.a.	303-25-3	
Dexmethylphenidate HCl	CNS stimulant	USP	USDMF	II	19262-68-1	
Dobutamine HCl	Vasopressor	Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	49745-95-1	
Dopamine HCl	Vasopressor	JP, Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	62-31-7	
Ephedrine HCl	Respiratory system	Ph. Eur., USP	CEP/USDMF	n.a.	50-98-6	
Ephedrine Sulphate	Respiratory system	USP	ASMF/USDMF	n.a.	134-72-5	
Fluoxetine HCl	Antidepressant	Ph. Eur., USP	CEP	n.a.	59333-67-4	
Hydrocodone Bitartrate	Analgesic, antitussive	USP	USDMF	II	34195-34-1	
Hydromorphone HCl	Analgesic	Ph. Eur., USP	CEP/USDMF	II	71-68-1	
Isotretinoin M	Dermatica	Ph. Eur., USP	CEP/USDMF	n.a.	4759-48-2	
Levomethadone HCl	Analgesic, opioid addiction	Ph. Eur.	CEP	II	125-58-6	
Levonordefrine Base	Vasoconstrictor	USP	USDMF	n.a.	829-74-3	

ASMF: Active Substance Mater File

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PharmaChemikalien  
Minden GmbH  
Germany

Siegfried St. Vulbas SAS  
France

Siegfried (Nantong)  
Pharmaceuticals Co. Ltd.  
China

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Levonordefrine HCl	Vasoconstrictor	n.a.	n.a.	n.a.	829-74-3	■
Mepivacaine HCl	Anesthetic	JP, Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	1722-62-9	■
Methadone HCl	Analgesic, opioid addiction	Ph. Eur., USP	CEP/USDMF	II	1095-90-5	▲ ●
Methenamine Hippurate	Antiseptic agent	USP	USDMF	n.a.	5714-73-8	■
Methylphenidate HCl	CNS stimulant	Ph. Eur., USP	CEP/USDMF	II	298-59-9	● ■
Metolazone	Cardiovascular agent	Ph. Eur., USP	ASMF/USDMF	n.a.	17560-51-9	■
Morphine Sulfate	Analgesic	Ph. Eur., USP	CEP/USDMF	II	6211-15-0	▲
Naloxone HCl	Opiate antagonist	Ph. Eur., USP	CEP/USDMF	n.a.	51481-60-8	◆
Naltrexone HCl	Opiate antagonist	Ph. Eur., USP	CEP/USDMF	n.a.	16676-29-2	◆
Nicotine	Smoking cessation	Ph. Eur., USP	CEP/USDMF	n.a.	54-11-5	▲
Nicotine Bitartrate	Smoking cessation	Ph. Eur., USP	CEP/USDMF	n.a.	65-31-6	▲
Nicotine Polacrilex	Smoking cessation	Ph. Eur., USP	CEP/USDMF	n.a.	96055-45-7	▲ ✕
Nifedipine	Antihypertensive	Ph. Eur.	CEP	n.a.	21829-25-4	▲
Oxiconazole Nitrate	Antifungal	n.a.	ASMF/USDMF	n.a.	64211-46-7	▲
Oxybutynin Base	Urinary antispasmodics	Ph. Eur., USP	ASMF/USDMF	n.a.	5633-20-5	■
Oxybutynin HCl	Urinary antispasmodics	Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	1508-65-2	■
Oxycodone HCl	Analgesic	Ph. Eur., USP	CEP/USDMF	II	124-90-3	▲ ●
Oxymetazoline HCl	Decongestant	JP, Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	2315-02-8	◆
Pentobarbital Sodium	Veterinary euthanasia, human sedative	USP	USDMF	II	57-33-0	●
Phenazine Sulphate	Antidepressant, anxiolytic (MAOI)	n.a.	USDMF	n.a.	156-51-4	■
Phenobarbital Sodium	Sedative, anticonvulsant, hypnotic	USP	USDMF	IV	57-30-7	●
Phentermine Base	Anorexic	USP	USDMF	IV	122-09-8	●
Phentermine HCl	Anorexic	USP	USDMF	IV	1197-21-3	●
Phenylephrine HCl	Respiratory system	IP, JP, Ph. Eur., USP	CEP/USDMF	n.a.	61-76-7	◆
Prilocaine Base	Anesthetic	Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	721-50-6	■
Prilocaine HCl	Anesthetic	Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	1786-81-8	■
Primidone	Antiepileptic	Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	125-33-7	▬
Proparacaine HCl	Ophthalmic, anesthetic	BP, USP	ASMF/USDMF	n.a.	5875-06-09	▲
Pseudoephedrine HCl	Respiratory system	JPC, Ph. Eur., USP	CEP/USDMF	n.a.	345-78-8	◆

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Pseudoephedrine Sulphate	Respiratory system	USP	ASMF/USDMF	n.a.	7460-12-0	◆
Secobarbital Sodium	Sedative	USP	USDMF	II	309-43-3	●
Tetracaine Base	Anesthetic	USP	ASMF/USDMF	n.a.	94-24-6	■
Tetracaine HCl	Anesthetic	JP, Ph. Eur., USP	ASMF/JDMF/ USDMF	n.a.	136-47-0	■
Theophylline Anhydrous	Respiratory system	IP, JP, Ph. Eur., USP	CEP/JDMF/USDMF	n.a.	58-55-9	◆
Theophylline Hydrous	Respiratory system	IP, JP, Ph. Eur., USP	CEP/USDMF	n.a.	5967-84-0	◆
Tretinoin M	Dermatica	Ph. Eur., USP	CEP/USDMF	n.a.	302-79-4	◆
Tricaine Methanesulfonate	Anesthetic	n.a.	ASMF	n.a.	886-86-2	■
Xylometazoline HCl	Decongestant	IP, Ph. Eur., USP	CEP/USDMF	n.a.	1218-35-5	◆

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## Development Portfolio Drug Substance

Development Products	Therapeutic Areas	Commercial Availability	Monographs	Regulatory Documentation	DEA Schedule	CAS Number
Naltrexone Base	Opiate antagonist	Standard	n.a.		n.a.	16590-41-3
Methadone Base	Analgesic, opioid addiction	Yes <sup>1</sup>	n.a.	In development	II	76-99-3
Methylphenidate Base	CNS stimulant	On request	USP	On request	II	113-45-1
Methylnaltrexone Bromide	Opiate antagonist	On request	n.a.	On request	n.a.	83387-25-1
Tapentadol	Analgesic	On request	n.a.	On request	II	175591-23-8

<sup>1</sup> Clinical Trial Material

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## Product List Oral Formulation

INN	Therapeutic Areas	Formulation / Dosage	CTD-Format Availability
Amlodipine Besylate	Hypertension	Tablet 5, 10 mg	Available
Amlodipine Mesylate	Hypertension	Tablet 5, 10 mg	Available
Candesartan Candesartan/HCT	Hypertension	Tablet 4, 8, 16, 32 mg 8/12.5, 16/12.5 mg	Available
Doxazosin	Hypertension	Tablet 1, 2, 4 mg	Available
Felodipine	Hypertension	SR Tablet 2.5, 5, 10 mg	Available
Finasteride	Benign Prostate Hyperplasia	Tablet 5 mg	Available
Fluoxetine	Depression	Capsule 10 mg Tablet 10 mg Tablet 20 mg	Available On request Available
Imatinib	Chronic Myeloid Leukaemia	Film-coated tablet 100, 400 mg	Available
Latanoprost	Glaucoma / Ocular Hypertension	Solution 2.5 ml (0.005%)	Available
Montelukast	Asthma	Chewable tablet 4, 5 mg Film-coated tablet 10 mg	Available Available
Nifedipine	Hypertension	SR Tablet 20, 40 mg	Available
Olanzapine	Schizophrenia / Bipolar Disorder	Orodispersible tablet 2.5, 5, 7.5, 10, 15, 20 mg	Available
Sitagliptin Sitagliptin/Metformin	Diabetes	Film-coated tablet 25, 50, 100 mg 50/500, 50/850, 50/1000 mg	In development
Tamsulosine	Benign Prostate Hyperplasia	XL Capsule 0.4 mg	Available

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Siegfried Malta Ltd, Malta

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# Product List Sterile Application

Dossier	Form	Concentration / Strength	Volume	Territory
Alfentanil inj.	Ampoule & Vial	0.5 mg/ml	1, 2, 10 ml	B
Apomorphine inj.	Ampoule	10 mg/ml	5 ml	A
Atracurium inj.	Ampoule	10 mg/ml	2.5 (3), 5 ml	B
Atracurium inj.	Ampoule	10 mg/ml	5 ml	B
Cisatracurium inj.	Ampoule	2 mg/ml	2, 5, 10 ml	B
Clindamycine inj.	Ampoule	150 mg/ml	2, 4, 6 ml	A
Dexamethasone inj.	Ampoule	4 mg/ml	1, 2, 5, 10 ml	B
Diazepam inj.	Ampoule	5 mg/ml	2 ml	A
Dobutamine inj.	Ampoule/Vial		5, 20, 50 ml	B
Fentanyl inj.	Ampoule	0.05 mg/ml	2, 10 ml	B
Flumazenil inj.	Ampoule	0.1 mg/ml	5, 10 ml	B
Furosemide inj.	Ampoule	10 mg/ml	2, 4, 25 ml	B
Glyceryl Trinitrate inj.	Ampoule, Vial	1 mg/ml	1, 10, 25, 50 ml	B
Granisetron inj.	Vial (single & multidose)	0.1, 1 mg/ml	1, 4 ml	A
	Ampoule	0.1, 1 mg/ml	3 ml	B
Ketamine inj.	Ampoule, Vial	10, 50 mg/ml	2, 5, 10, 20 ml	B
Levofloxacin inj.	Vial	5 mg/ml	50, 100 ml	A
Methotrexate	Prefilled syringe	25 mg/ml	0.3(0.5), 0.4(0.5), 0.6(1), 0.8(1) ml, 1(1) ml	C
Metoclopramide inj.	Ampoule	5 mg/ml	2, 10 mg	B
Midazolam inj.	Ampoule	1, 2, 5 mg/ml	1, 2, 3, 5, 10, 18, 25 ml	B
Morphine Sulfate inf.	Vial, Ampoule	1, 2, 10, 15, 20 mg/ml	1, 5, 10, 50, 100 ml	B
Naloxone inj.	Ampoule	0.02, 0.4 mg/ml	1, 2 ml	B
Neostigmine	Ampoule	0.5, 2.5 mg/ml	1 ml	A
Ondansetron inj.	Vial (single & multidose)	2 mg/ml	2 ml, 20 ml	A
	Ampoule	2 mg/ml	2 ml, 4 (5) ml	B
Levofloxacin inj.	Vial	5 mg/ml	100 ml	A
Palonosetron	Vial	5 µg/ml	5 ml	A
Pethidine inj.	Ampoule	50 mg/ml	1, 2 ml	A
Remifentanil inj.	Vial (lyo)	1, 2, 5 mg		B
Rocuronium inj.	Vial	10 mg/ml	2.5 (2), 5 (6), 10 ml	B
Sufentanil inj.	Ampoule	0.005, 0.05 mg/ml	1, 2, 5, 10, 15, 20 ml	B
Thioctacid inj.	Ampoule/Bottle	25 mg/ml / 6, 12 mg/ml	12, 24, 50, 100 ml	A
Tramadol inj.	Ampoule	50 mg/ml	1, 2 ml	B
Zoledronic acid	Plastic vial	4 mg/5 ml	5 ml	B

Territory A: Worldwide  
 Territory B: Worldwide excluding the below mentioned countries: Austria, Denmark, Germany, Finland, France, Great Britain, Greece, Ireland, Spain, Italy, The Netherlands, Norway, Portugal, Sweden, Switzerland, Turkey, Brazil, Mexico, Chile, Panama, Venezuela, Colombia, Canada, Israel, Jordan, Kuwait, Lebanon, Saudi Arabia, UAE, Yemen, Bahrain, Oman, Hong Kong, Indonesia, Malaysia, Pakistan, Singapore, Sri Lanka, Vietnam, New Zealand, Australia, Thailand, Taiwan, Philippines, Libya, Kenya, Egypt, Republic of South Africa (South Africa with respect to the Dossiers relating to Remifentanil, Alfentanil, Rocuronium and Cisatracurium only)  
 Territory C: Europe

Siegfried Hameln, Germany

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 please contact us at [sales@siegfried.ch](mailto:sales@siegfried.ch)

## Marketing Authorizations

Dossier	Form	Concentration / Strength	Volume
Apomorphine inj.	Ampoule	10 mg/ml	5 ml
Epirubicin inj.	Vial	2 mg/ml	5, 10, 25, 50, 100 ml
Irinotecan inj.	Vial	20 mg/ml	2, 5, 15, 25 ml
Paricalcitol inj.	Ampoule	5 mcg/ml	1.2 ml
Remifentanil inj.	Powder for Inj., Ampoule	1, 2, 5 mg	

## Pending Marketing Authorizations

Dossier	Form	Concentration / Strength	Volume
Apomorphine inj.	Ampoule	10 mg/ml	5 ml

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