




**40 Years**  
of health, life and  
everything in between.

# CATALOGUE

## 2017-2018



The image features the word "TECHNOLOGIES" in a white, thin, sans-serif font, centered horizontally. Behind the text is a large, dark green graphic element consisting of a semi-circle on the left and a square on the right, forming a shape reminiscent of a stylized 'D' or a bracket. The background is a gradient of green, transitioning from a lighter shade on the left to a darker shade on the right. There are also some faint, thin white lines and shapes that appear to be part of a larger design or layout.

TECHNOLOGIES



# CUTTING-EDGE TECHNOLOGY AND HIGH INDUSTRIAL CAPACITY

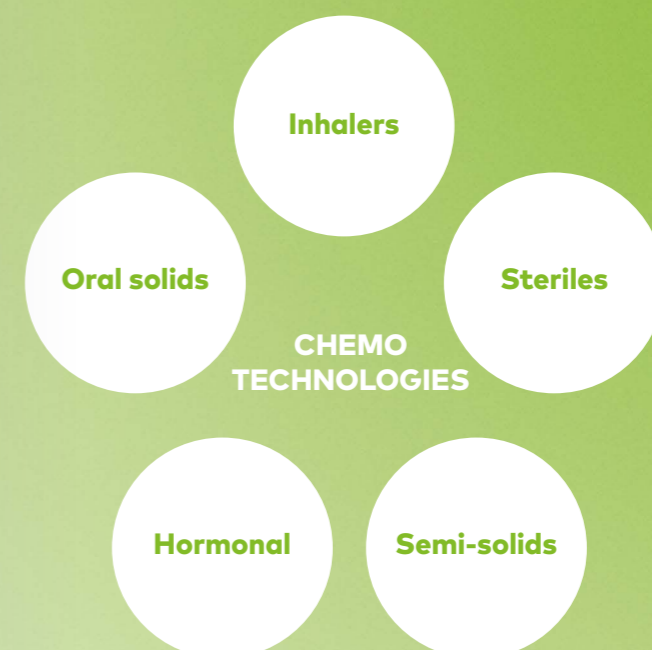
Chemo has FDF manufacturing plants with the most advanced and sophisticated technologies in immediate-release and modified-release solids in both tablets and capsules, with specific areas for soft capsules, foam products, semi-solids and osmotic delivery systems, as well as an entire building dedicated to respiratory products.

Chemo has one of the largest fluid beds in the world, with a capacity of 1,300 kg. per batch.

In addition, our company is capable of manufacturing any type of hormone product, including granules, oral and vaginal tablets, soft capsules, hormone creams and vaginal rings.

Moreover, Chemo is specialised in manufacturing steroids and proton pump inhibitors.

As part of our reinvestment and continuous improvement, at Chemo, we have just opened two injectable plants in Spain and another one in India dedicated to oral solid dosage forms that will provide solutions using the latest technology and in accordance with the highest quality standards.



# ORAL SOLID TECHNOLOGIES



**1\_ Powder Filled Capsules.**

Wide range of sizes and color combinations.

**2\_ Pellet Filled Capsules.**

Wide range of sizes and color combinations.

**3\_ Coated Tablets.**

Including functional coating and aesthetic coating. Immediate and Controlled Release.

**4\_ Bilayer Tablets.**

Allows formulation of two different APIs. 2 IRs or IR+CR/SR fixed-dose combination.

**5\_ Matrix Tablets.**

Controlled-release technology.

**6\_ Min-Tablets filled in Capsules.**

Immediate Release or Controlled Release.

**7\_ Osmotic Tablets.**

Slow extended-release profiles (controlled/sustained release), zero-order.

**8\_ Soft Gelatine Capsules.**

**6,000 M**  
CAPSULES

**1.5 M**  
PELLETS (Kg)

**2,000 M**  
TABLETS

**400 M**  
SOFT GEL  
CAPSULES

# INHALATION TECHNOLOGIES



**9\_ DPI.**

Dry Powder Inhalers based on monodose capsules.

**10\_ SMI.**

Soft Mist Inhalers generating a soft mist containing a high fine particle fraction.

**1,000 M**  
CAPSULES  
FOR INHALATION

# HORMONAL TECHNOLOGIES



**11\_ Tablets.**

Oral Contraceptives for all consumption regimes. i.e. 21+7, 24+4, 84+7 and others.

**12\_ Chewable Tablets.**

Oral Contraceptives single or fixed-dose combinations.

**13\_ Vaginal Tablets with applicator.**

**14\_ Intravaginal Rings.**

Controlled release technology with delivery from 1 up to 3 months.

**15\_ Oral Soft Gelatine Capsules.**

**16\_ Intravaginal Soft Gelatin Capsules.**

**3,000 M**  
TABLETS

**300 M**  
CAPSULES

**4 M**  
VAGINAL RINGS



# INJECTABLE TECHNOLOGIES



17 \_ Aqueous Solutions in both Glass vials and Syringes

18 \_ Oily Solutions in both Glass vials and Syringes

19 \_ Lyophilized Vials

20 \_ Aqueous suspensions in both Glass vials and Syringes  
(Glass or polymeric)

**60 M**  
VIALS



**60 M**  
SYRINGES

**30 M**  
SYRINGES EACH PLANT

**45 M**  
VIALS UNIVERSAL



**15 M**  
VIALS FARMALAN

# SEMISOLIDS TECHNOLOGIES



21 \_ Gels.  
(Aqueous and oily gels)

22 \_ Creams.  
(Emulsions in suspension, emulsions in solution, water in oil (w/o)  
& oil in water (o/w).

23 \_ Ointments.  
(Hydrophilic & hydrophobic ointments).

24 \_ Foams.  
(Based on solution or emulsion formulations).

**190 M**  
SEMI-SOLIDS



PRODUCT

LIST







# EXPERTS IN THE ENTIRE PHARMACEUTICAL VALUE



40 Years of health, life and everything in between.

## INDEX




### API PORTFOLIO

-  Quimica Sintetica
-  Industriale Chimica
-  Maprimed
-  Nosch Laboratories






### API PIPELINE

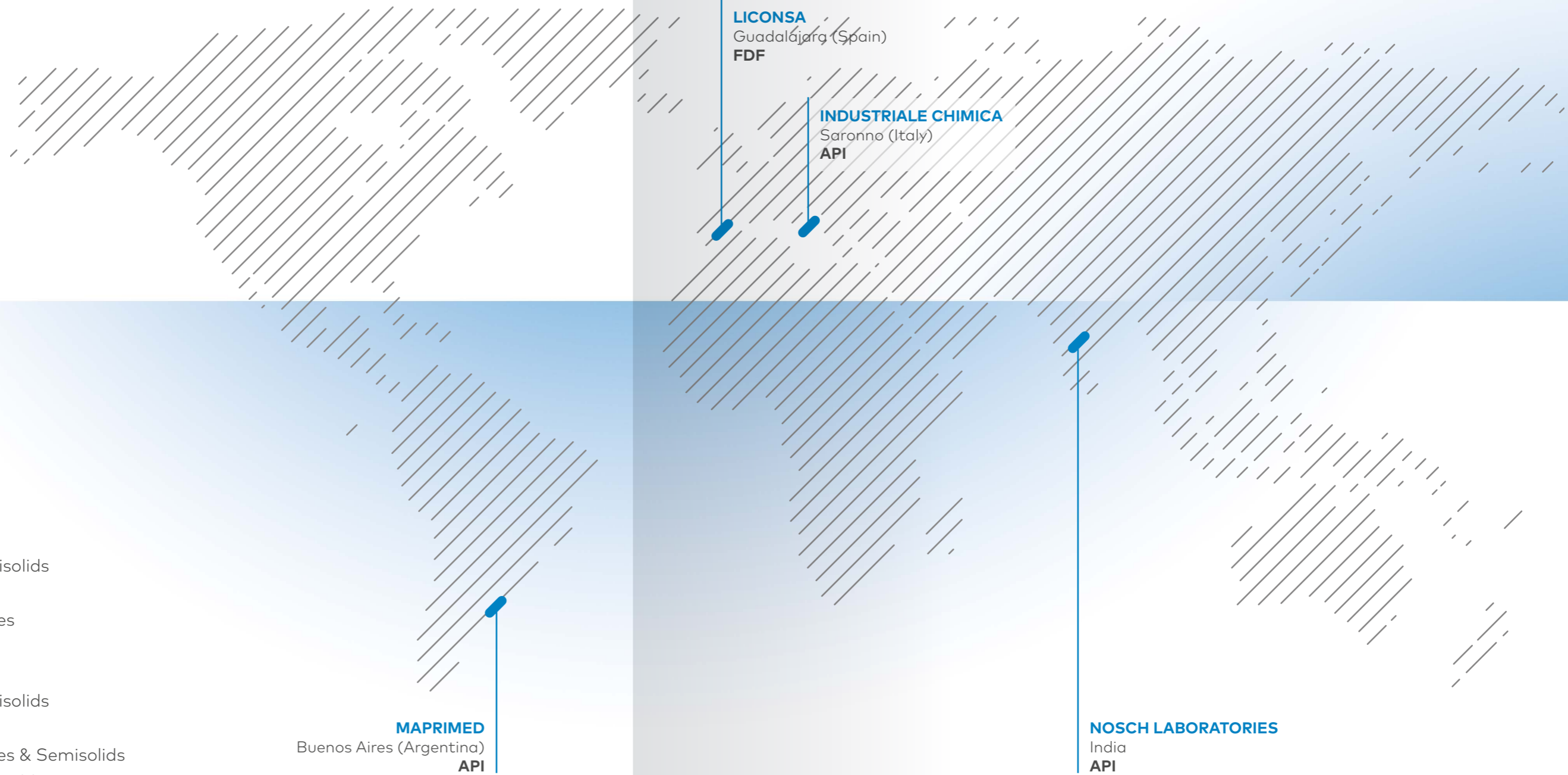
-  Quimica Sintetica
-  Industriale Chimica
-  Maprimed
-  Nosch Laboratories
-  Universal Farma
-  Tyche
-  SMS
-  Under evaluation

### FDF PORTFOLIO

-  Liconsa - Solids & Semisolids
-  Liconsa - Respiratory
-  Leon Farma - Hormones

### FDF PIPELINE

-  Liconsa - Solids & Semisolids
-  Liconsa - Respiratory
-  Leon Farma - Hormones & Semisolids
-  Universal Farma - Injectables
-  Farmalan - Hormonal Injectables



**QUIMICA SINTETICA**  
Alcala de Henares (Spain)  
API

**LEON FARMA**  
Leon (Spain)  
FDF

**FARMALAN**  
Leon (Spain)  
FDF

**UNIVERSAL FARMA**  
Guadalajara (Spain)  
FDF

**LICONSA**  
Guadalajara (Spain)  
FDF

**INDUSTRIALE CHIMICA**  
Saronno (Italy)  
API

**MAPRIMED**  
Buenos Aires (Argentina)  
API

**NOSCH LABORATORIES**  
India  
API

## QUIMICA SINTETICA

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Analgesics & Anti-Inflammatories	CELECOXIB	Arthritis, Osteoarthritis, Rheumatoid Arthritis	CEP/DMF
Analgesics & Anti-Inflammatories	KETOROLAC TROMETHAMINE	Acute Pain	DMF
Analgesics & Anti-Inflammatories	MELOXICAM	Arthritis, Osteoarthritis, Rheumatoid Arthritis	DMF
Anti-Infectives	ACYCLOVIR	Viral Infection	CEP/DMF
Anti-Infectives	AZITHROMYCIN	Bacterial Infection	DMF
Anti-Infectives	CHLORAMPHENICOL	Bacterial Infection	DMF
Anti-Infectives	CIPROFLOXACIN	Bacterial Infection	CEP/DMF
Anti-Infectives	CIPROFLOXACIN HYDROCHLORIDE	Bacterial Infection	CEP/DMF
Anti-Infectives	FLUCONAZOLE	Fungal Infection	CEP/DMF
Anti-Infectives	ITRACONAZOLE	Fungal Infection	CEP/DMF
Anti-Infectives	KETOCONAZOLE	Fungal Infection	DMF
Anti-Infectives	LEVOFLOXACIN	Bacterial Infection	DMF
Anti-Infectives	MICONAZOLE NITRATE	Fungal Infection	DMF
Anti-Infectives	TELAPREVIR	Viral Infection	DMF
Anti-Infectives	TERBINAFINE HYDROCHLORIDE	Fungal Infection	CEP/DMF
Anti-Infectives	TERCONAZOLE	Fungal Infection	DMF
Cardiovascular	BARNIDIPINE HYDROCHLORIDE	Hypertension	DMF
Cardiovascular	BENAZEPRIL HYDROCHLORIDE	Hypertension	DMF
Cardiovascular	BUMETANIDE	Fluid Retention (edema)	CEP/DMF
Cardiovascular	CANDESARTAN CILEXETIL	Hypertension	CEP/DMF
Cardiovascular	CAPTOPRIL	Hypertension	DMF
Cardiovascular	FLECAINIDE ACETATE	Arrhythmia	CEP
Cardiovascular	GUANFACINE HYDROCHLORIDE	Hypertension	DMF
Cardiovascular	INDAPAMIDE	Hypertension & Fluid Retention (edema)	DMF
Cardiovascular	IRBESARTAN	Hypertension	DMF
Cardiovascular	ISRADIPINE	Hypertension	DMF
Cardiovascular	IVABRADINE	Acute Coronary Syndrome	DMF
Cardiovascular	LOSARTAN POTASSIUM	Hypertension	DMF
Cardiovascular	PERINDOPRIL TERT-BUTYLAMINE	Hypertension	DMF
Cardiovascular	RIVAROXABAN	Deep Vein Thrombosis	DMF
Cardiovascular	TELMISARTAN	Hypertension	DMF
Cardiovascular	VALSARTAN	Hypertension	DMF
CNS	ASENAPINE MALEATE	Schizophrenia	DMF
CNS	FLUOXETINE HYDROCHLORIDE	Depression	DMF
CNS	LEVOMILNACIPRAN	Depression	DMF
CNS	PALIPERIDONE PALMITATE	Schizophrenia	DMF
CNS	SUMATRIPTAN BASE	Migraine	DMF
CNS	SUMATRIPTAN SUCCINATE	Migraine	CEP/DMF
CNS	TIANEPTINE SODIUM	Depression	CEP/DMF
CNS	VENLAFAXINE HCL	Depression	CEP
CNS	ZOLPIDEM TARTRATE	Sedative & Hypnotic	DMF
Gastroenterology	FAMOTIDINE	Peptic Ulcer	DMF
Gastroenterology	LANSOPRAZOLE	Peptic Ulcer	CEP/DMF
Gastroenterology	OMEPRAZOLE	Peptic Ulcer	CEP/DMF
Gastroenterology	PANTOPRAZOLE SODIUM	Peptic Ulcer	DMF
Gastroenterology	RABEPRAZOLE SODIUM	Peptic Ulcer	CEP/DMF
Gastroenterology	RANITIDINE	Peptic Ulcer	CEP/DMF
Ophthalmologicals	OFLOXACIN	Eye Bacterial Infection	CEP/DMF
Other Hormone Disorders	TAMSULOSIN HYDROCHLORIDE	Benign Prostatic Hyperplasia	DMF
Other Therapies	FEBUXOSTAT	Gout	DMF
Respiratory	LORATADINE	Allergy Symptoms	CEP/DMF
Respiratory & Ophthalmologicals	NEDOCROMIL SODIUM	Asthma & Ophthalmologicals	DMF
Veterinarian	PRAZIQUANTEL	Sedative & Hypnotic	CEP/DMF

## INDUSTRIALE CHIMICA

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Analgesics & Anti-Inflammatories	PENTAZOCINE HYDROCHLORIDE	Acute Pain	DMF
Cardiovascular	ALPROSTADIL	Erectile Dysfunction	DMF
Cardiovascular	BUMETANIDE	Fluid Retention (edema)	CEP/DMF
Cardiovascular	DOFETILIDE	Arrhythmia	DMF
Cardiovascular	EPLERENONE	Hypertension, Chronic Heart Failure	CEP filed/DMF
Cardiovascular	INDAPAMIDE	Hypertension & Diuretic	CEP/DMF
Cardiovascular	MIDODRINE	Hypotension	DMF
Cardiovascular	PHENTOLAMINE MESYLATE	Hypertension	CEP/DMF
CNS	DALFAMPRIDINE	Multiple Sclerosis	DMF
CNS	IDEBENONE	Nootropic	DMF
CNS	MEMANTINE HYDROCHLORIDE	Alzheimer	DMF
CNS	ZOPICLONE	Sedative & Hypnotic	CEP/DMF
Hormonal - Contraceptive	DESOGESTREL	Contraception	CEP/DMF
Hormonal - Contraceptive	DIENOGEST	Contraception	CEP filed/DMF
Hormonal - Contraceptive	DROSPIRENONE	Contraception	CEP/DMF
Hormonal - Contraceptive	ETHINYL ESTRADIOL	Contraception	CEP/DMF
Hormonal - Contraceptive	ETONOGESTREL	Contraception	DMF
Hormonal - Contraceptive	GESTODENE	Contraception	CEP/DMF
Hormonal - Contraceptive	LEVONORGESTREL	Contraception	CEP/DMF
Hormonal - Contraceptive	LEVONORGESTREL BUTYRATE	Contraception	DMF
Hormonal - Contraceptive	NOMEGESTROL	Contraception	DMF
Hormonal - Contraceptive	NORGESTIMATE	Contraception	DMF
Hormonal - Contraceptive	TRIMEGESTONE	Contraception	DMF
Ophthalmologicals	BIMATOPROST	Glaucoma	DMF
Ophthalmologicals	BRINZOLAMIDE	Glaucoma	DMF
Ophthalmologicals	LATANOPROST	Glaucoma	DMF
Ophthalmologicals	LOTEPREDNOL ETABONATE	Eye swelling	DMF
Ophthalmologicals	SULFAMETHYLTHIAZOL	Ophthalmologicals	DMF
Ophthalmologicals	TAFLUPROST	Glaucoma	DMF
Ophthalmologicals	TRAVOPROST	Glaucoma	DMF
Other Hormone Disorders	ABIRATERONE ACETATE	Prostate Cancer	DMF
Other Hormone Disorders	FULVESTRANT	Breast Cancer	CEP/DMF
Other Hormone Disorders	TIBOLONE	Hormone Replacement Therapy	CEP/DMF
Respiratory	FENOTEROL	Asthma & COPD	DMF
Respiratory	FLUTICASON PROPIONATE	Asthma	CEP/DMF
Respiratory	FORMOTEROL FUMARATE	Asthma & COPD	CEP/DMF
Respiratory	INDACATEROL	COPD	DMF
Respiratory	MOMETASON FUROATE (ANH & MONOH)	Asthma	DMF
Respiratory	ROFLUMILAST	COPD	DMF
Respiratory	SALMETEROL XINAFOATE	COPD	CEP/DMF
Respiratory	TIOTROPIUM MONOHYDRATE	Asthma & COPD	CEP filed/DMF
Respiratory	TIOTROPIUM SOLVATE	Asthma & COPD	DMF
Respiratory & Digestive System	BUDESONIDE	Asthma & Crohn disease	CEP/DMF
Veterinarian	ALTRENOGEST	Contraceptive	DMF/VMF
Veterinarian	DL-CLOPROSTENOL	Contraceptive	VMF

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# API PORTFOLIO

## MAPRIMED

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Analgesics & Anti-Inflammatories	CLONIXIN LYSINATE	Acute Pain	DMF
Cardiovascular	ENALAPRIL MALEATE	Hypertension	DMF
Cardiovascular	FLECAINIDE ACETATE	Arrhythmia	CEP/DMF
Cardiovascular	IVABRADINE	Acute Coronary Syndrome	DMF
Cardiovascular	LOSARTAN POTASSIUM	Hypertension	DMF
Cardiovascular	PRASUGREL HYDROCHLORIDE	Acute Coronary Syndrome	DMF
CNS	ARIPIRAZOLE	Antipsychotic	DMF
CNS	CLOXAZOLAM	Sedative, Hypnotic and Anxiolytic	DMF
CNS	ESZOPICLONE	Sedative and Hypnotic	DMF
CNS	FINGOLIMOD HYDROCHLORIDE	Multiple Sclerosis	DMF
CNS	LACOSAMIDE	Epilepsy	DMF
CNS	PALIPERIDONE	Schizophrenia	DMF
CNS	RASAGILINE MESYLATE	Parkinson	DMF
CNS	ZOPICLONE	Sedative & Hypnotic	CEP/DMF
Endocrinology	LORCASERINE	Obesity	DMF
Human & Veterinarian	BENZNIDAZOLE	Chagas / Antiparasitic Agent	DMF
Ophthalmologicals	BIMATOPROST	Glaucoma	DMF
Ophthalmologicals	BRINZOLAMIDE	Glaucoma	DMF
Other Therapies	IBANDRONATE SODIUM	Osteoporosis	DMF
Other Therapies	ZOLEDRONIC ACID MONOHYDRATE	Osteoporosis	DMF
Respiratory	TIOTROPIUM SOLVATE	Asthma & COPD	DMF
Urology	SILDENAFIL CITRATE	Erectile Dysfunction Agent	CEP/DMF



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## NOSCH LABORATORIES

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Analgesics & Anti-Inflammatories	KETOROLAC TROMETHAMINE	Acute Pain	DMF
Anti-Infectives	ITRACONAZOLE	Fungal Infection	CEP/DMF
Anti-Infectives	LINEZOLID	Bacterial Infection	DMF
Anti-Infectives	MOXIFLOXACIN BASE	Bacterial Infection	DMF
Anti-Infectives	MOXIFLOXACIN HCL ANHYDROUS	Bacterial Infection	CEP/DMF
Anti-Infectives	MOXIFLOXACIN HCL MONOHYDRATE	Bacterial Infection	DMF
Anti-Infectives	TERCONAZOLE	Fungal Infection	DMF
Cardiovascular	ALISKIREN HEMIFUMARATE	Hypertension	DMF
Cardiovascular	DABIGATRAN	Anticoagulant	DMF
Cardiovascular	DOXAZOSIN MESYLATE	Hypertension	DMF
Cardiovascular	DRONEDARONE HYDROCHLORIDE	Arrhythmia	DMF
Cardiovascular	ENALAPRIL MALEATE	Hypertension	DMF
Cardiovascular	RIVAROXABAN	Deep Vein Thrombosis	DMF
Cardiovascular	ROSUVASTATIN CALCIUM	Hypercholesterolaemia	DMF
CNS	ALMOTRIPTAN MALATE	Migraine	DMF
CNS	DONEPEZIL HYDROCHLORIDE	Alzheimer	DMF
CNS	DULOXETINE HYDROCHLORIDE	Depression	CEP/DMF
CNS	ELETRIPTAN HYDROBROMIDE	Migraine	DMF
CNS	MEMANTINE HYDROCHLORIDE	Alzheimer	DMF
CNS	NARATRIPTAN HYDROCHLORIDE	Migraine	DMF
CNS	OLANZAPINE	Schizophrenia	CEP/DMF
CNS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	Parkinson	DMF
CNS	PREGABALIN	Epilepsy	DMF
CNS	QUETIAPINE FUMARATE	Schizophrenia	CEP/DMF
CNS	RASAGILINE MESYLATE	Parkinson	DMF
CNS	RIZATRIPTAN BENZOATE	Migraine	DMF
CNS	SERTRALINE HYDROCHLORIDE	Depression	DMF
CNS	SUMATRIPTAN SUCCINATE	Migraine	DMF
CNS	ZOLMITRIPTAN	Migraine	DMF
Endocrinology	SIBUTRAMINE HCl	Obesity	DMF
Gastroenterology	DEXLANSOPRAZOLE	Peptic Ulcer	DMF
Gastroenterology	DEXRABEPRAZOLE SODIUM	Peptic Ulcer	DMF
Gastroenterology	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	Peptic Ulcer	CEP/DMF
Gastroenterology	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	Peptic Ulcer	CEP/DMF
Gastroenterology	ESOMEPRAZOLE SODIUM	Peptic Ulcer	DMF
Gastroenterology	LANSOPRAZOLE	Peptic Ulcer	CEP/DMF
Gastroenterology	OMEPRAZOLE	Peptic Ulcer	DMF
Gastroenterology	OMEPRAZOLE MAGNESIUM	Peptic Ulcer	DMF
Gastroenterology	OMEPRAZOLE SODIUM	Peptic Ulcer	DMF
Gastroenterology	PANTOPRAZOLE MAGNESIUM DIHYDRATE	Peptic Ulcer	DMF
Gastroenterology	PANTOPRAZOLE SODIUM	Peptic Ulcer	CEP/DMF
Gastroenterology	RABEPRAZOLE SODIUM	Peptic Ulcer	DMF
Other Hormone Disorders	TAMSULOSIN HYDROCHLORIDE	Benign Prostatic Hyperplasia	DMF
Other Therapies	IMATINIB MESYLATE	Neoplasia	DMF
Urology	DAPOXETINE HYDROCHLORIDE	Premature Ejaculation	DMF

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# API PIPELINE



40 Years  
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## QUIMICA SINTETICA

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Anti-Infectives	EFINACONAZOLE	Antifungal	✓	✓	4Q17	2Q18
Anti-Infectives	POSACONAZOLE	Fungal Infection	✓	✓	4Q17	1Q18
Anti-Infectives	SOFOSBUVIR	Hepatitis C	✓	✓	TBD	TBD
Cardiovascular	ENTRESTO	Heart Failure	✓	✓	4Q17	2Q18
CNS	BREXPIRAZOLE	Schizophrenia	✓	✓	4Q17	3Q18
CNS	DROXIDOPA	Parkinson	✓	✓	✓	1Q18
CNS	TASIMELTEON	Non 24-Hour Sleep-Wake Disorder	✓	✓	4Q17	2Q18
Gastroenterology	ELUXADOLINE	Irritable bowel syndrome	✓	4Q17	1Q18*	3Q18*
Other Therapies	APREMILAST	Psoriasis	✓	✓	✓	4Q17

## INDUSTRIALE CHIMICA

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
CNS	RAMELTEON	Insomnia	✓	✓	4Q17	2Q18
Other Hormone Disorders	DYDROGESTERONE	Progesterone deficiency	✓	✓	4Q17	2Q18
Other Hormone Disorders	ULIPRISTAL	Emergency Contraception	✓	✓	4Q17	1Q18
Other Therapies	OBETICHOIC ACID	Primary Biliary Cirrhosis	✓	✓	4Q17	2Q18
Respiratory	BECLOMETHASONE	COPD & Asthma	✓	✓	4Q17	1Q18*
Respiratory	FLUTICASON FUROATE	Asthma	✓	✓	✓	1Q18
Respiratory	GLYCOPYRROLATE	Antispasmodic & Antisialagogue	✓	✓	✓	4Q17
Respiratory	OLODATEROL	COPD	✓	4Q17	3Q18	1Q19
Respiratory	VILANTEROL	COPD	✓	✓	TBD	TBD

## MAPRIMED

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
CNS	CARIPRAZINE	Schizophrenia	✓	✓	4Q17	2Q18
Human & Veterinarian	NITAZOXANIDE	Antiparasitic Agent	✓	✓	✓	2/3Q18

## NOSCH LABORATORIES

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Anti-Infectives	AMOROLFINE HCl	Fungal Infection	✓	✓	✓	4Q17
Cardiovascular	PITAVASTATIN	Hypercholesterolaemia	✓	✓	✓	4Q17
Endocrinology	GLIMEPIRIDE	Diabetes	✓	✓	✓	4Q17

## UNIVERSAL FARMA

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
CNS	ARIPRAZOLE (Sterile)	Schizophrenia	1Q18	2Q18	TBD	TBD
CNS	PALIPERIDONE PALMITATE (Sterile)	Schizophrenia	✓	✓	4Q17	2Q18
Ophthalmologicals	BRINZOLAMIDE (Sterile)	Glaucoma	1Q18	2Q18	TBD	TBD
Ophthalmologicals	LOTEPREDNOL (Sterile)	Eye swelling	1Q18	2Q18	TBD	TBD
Respiratory & Digestive	BUDESONIDE (Sterile)	Asthma & Crohn disease	4Q17	1Q18	TBD	TBD

## TYCHE

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Respiratory	NINTEDANIB	Idiopathic pulmonary fibrosis	✓	✓	4Q17	2Q18
Respiratory	PIRFENIDONE	Pulmonary fibrosis	✓	✓	✓	4Q17

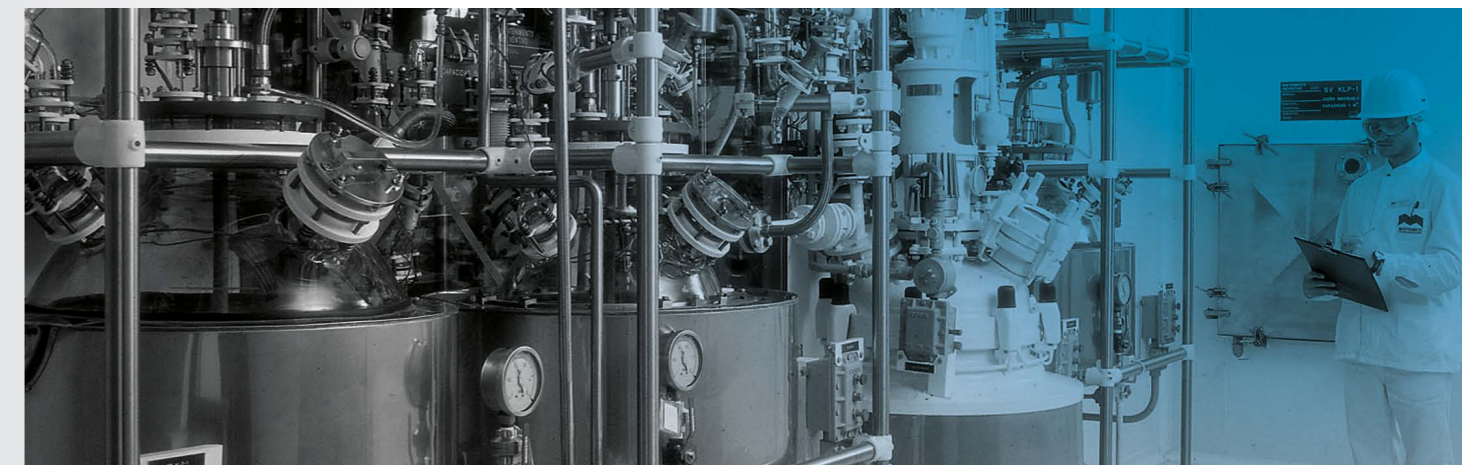
## SMS

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Cardiovascular	RANOLAZINE	Heart Failure	✓	✓	✓	4Q17
CNS	PERAMPANEL	Epilepsy	✓	✓	1Q18	2Q18
Endocrinology	CANAGLIFLOZIN	Diabetes	TBD	TBD	TBD	TBD
Endocrinology	DAPAGLIFLOZIN	Diabetes	4Q17	1Q18	3Q18	1Q19
Endocrinology	EMPAGLIFLOZIN	Diabetes	4Q17	4Q17	2Q18	4Q18
Endocrinology	LINAGLIPTIN	Diabetes	4Q17	4Q17	2Q18	4Q18
Endocrinology	SITAGLIPTIN HCL	Diabetes	✓	✓	✓	4Q17
Endocrinology	SITAGLIPTIN PHOSPHATE	Diabetes	✓	4Q17	4Q17	2Q18
Endocrinology	VILDAGLIPTIN	Diabetes	✓	✓	✓	4Q17
Urology	MIRABEGRON	Incontinence	✓	✓	4Q17	2Q18

## APIs UNDER EVALUATION

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Cardiovascular	SELEXIPAG	Pulmonary arterial hypertension	✓	4Q17	1Q18*	3Q18*
CNS	EDARAVONE	ALS & heart failure	✓	1Q18	2Q18*	4Q18*
CNS	OZANIMOD	Multiple Sclerosis	1Q18	2Q18	TBD	TBD
Endocrinology	ERTUGLIFLOZIN	Diabetes	TBD	TBD	TBD	TBD
Ophthalmologicals	NETARSUDIL	Glaucoma	TBD	TBD	TBD	TBD
Other Therapies	LESINURAD	Gout	✓	4Q17	1Q18*	3Q18*

\* pending on the prioritization of the project



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## SOLIDS

NAME	BRAND NAME (REFERENCE)	ATC-INDICATION	PHARMACEUTICAL FORM	DETAILS STRENGTH
ARIPIRAZOLE (EU)	Abilify®	N05A ANTIPSYCHOTICS	Tablets	5mg, 10mg, 15mg, 30mg
CANDESARTAN (EU)	Atacand®	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Tablets	8mg, 16mg, 32mg
CANDESARTAN + HCTZ (EU)	Atacand Hct®	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Tablets	8/12,5mg, 16/12,5mg, 32/12,5mg, 32/25mg
DULOXETINE (EU)	Cymbalta®	N06A ANTIDEPRESSANTS	Capsules-Pellets	30mg, 60mg
DUTASTERIDE (EU)	Avodart®	G04C DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	Soft Gelatin Capsule	0.5mg
EPLERENONE (EU)	Inspira®	C03D POTASSIUM-SPARING AGENTS	Tablets	25mg, 50mg
FLECAINIDE SR (EU)	Tambacor/ Flecaine®	C01B ANTIARRHYTHMICS, CLASS I AND III	Capsules-Minitabs	50mg, 100mg, 150mg, 200mg
IBANDRONATE 150MG (EU)	Bonviva®	M05B DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	Tablets	150 mg
IRBESARTAN (EU)	Aprovel®	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Tablets	75mg, 150mg, 300mg
IRBESARTAN + HCTZ (EU)	Aprovel Hct®	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Tablets	150mg/12,5mg; 300mg/12,5mg, 300mg/25mg
ITRACONAZOLE (EU)	Sporanox®	J02A ANTIMYCOTICS FOR SYSTEMIC USE	Capsules-Pellets	100mg
IVABRADINE (EU)	Procoralan, Coralan, Corlentor®	C01E OTHER CARDIAC PREPARATIONS	Tablets	5mg, 7,5mg
LANSOPRAZOLE (EU)	Prevacid®	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Capsules-Pellets	15mg, 30mg
LEVOFLOXACIN (ROW)	Tavanic®	J01M QUINOLONE ANTIBACTERIALS	Tablets	250mg, 500mg
LOSARTAN (EU)	Cozaar®	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Tablets	12,5mg, 25mg, 50mg, 100mg
LOSARTAN + HCTZ (EU)	Cozaar Plus®	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Tablets	100/25mg; 50/12,5mg
OMEPRAZOLE (EU)	Losec®	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Capsules-Pellets	10mg, 20mg, 40mg
PREGABALINE CAPSULES (EU)	Lyrica®	N03AX16 Antiepileptics	Capsules-Powder	25, 50, 75, 100, 150, 200, 225, 300 mg
RABEPRAZOLE (EU)	Pariet®	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Tablets	10mg, 20mg
SILDENAFIL (EU)	Viagra®	G04B UROLOGICALS	Tablets	25mg, 50mg, 100mg
TELMISARTAN (EU)	Micardis®	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Tablets	20mg, 40mg, 80mg
TELMISARTAN + HCTZ (EU)	Micardis Hct®	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Tablets	40/12,5mg, 80/12,5mg, 80/25mg
TERBINAFINE (EU)	Lamisil®	D01B ANTIFUNGALS FOR SYSTEMIC USE	Tablets	250 mg
TIANEPTINE (EU)	Stablon®	N06A ANTIDEPRESSANTS	Tablets	12,5mg
VALSARTAN (EU)	Diovan®	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Tablets	40mg, 80mg, 160mg, 320mg
VALSARTAN + HCTZ (EU)	Co Diovan®	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Tablets	80/12,5mg, 160/12,5mg, 160/25mg
VENLAFAXINE (EU)	Effexor®	N06A ANTIDEPRESSANTS	Osmotic tablet	37,5mg, 75mg, 150mg, 225 mg, 300mg

NOTE: Some of these active ingredients could be protected by a patent in force and would be therefore developed exclusively for the purposes stated in Article 10.6 of the Directive 2001/83/EC as amended by the Directive 2004/27/EC (Bolar provision). No activity will be performed with the active ingredients protected by a patent in force beyond the scope of the Bolar provision in any concerned jurisdiction. None of the active ingredients will be offered for sale or supply in countries where these activities fall within the scope of third party's patent rights.

## SEMISOLIDS

NAME	BRAND NAME (REFERENCE)	ATC-INDICATION	PHARMACEUTICAL FORM	DETAILS STRENGTH
LACTIC ACID (EU)	Geliofil®	G01A ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS	Cream	7 x 5mL; 5 x 5ml
TERBINAFINE CREAM (EU)	Lamisil®	D01A ANTIFUNGALS FOR TOPICAL USE	Cream	1%

## RESPIRATORY

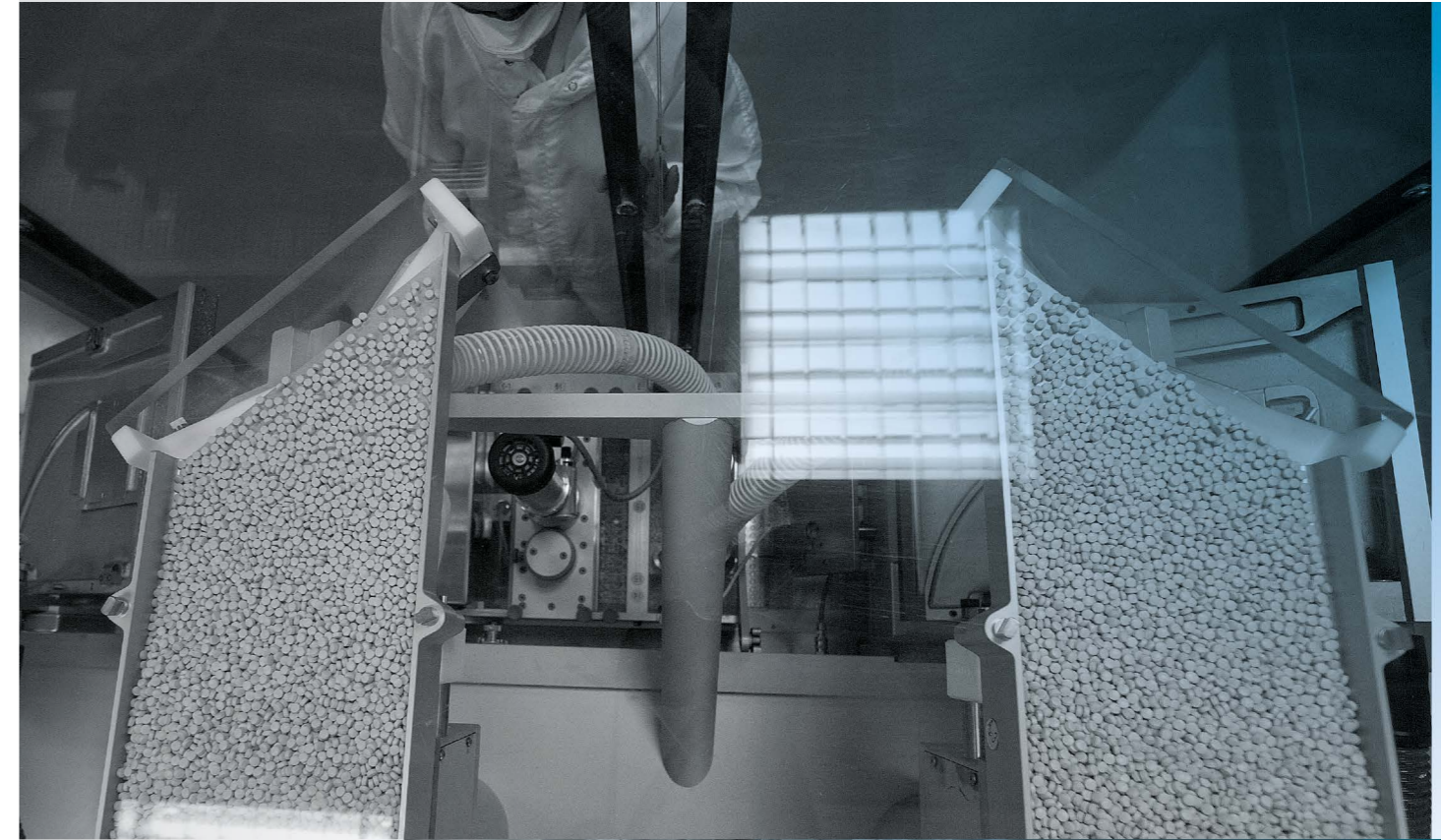
NAME	BRAND NAME (REFERENCE)	ATC-INDICATION	PHARMACEUTICAL FORM	DETAILS STRENGTH
BUDESONIDE + FORMOTEROL (ROW)	Foraseq®	R03A ADRENERGICS, INHALANTS	Capsules-Powder for Inhalation	400mcg /12mcg
FLUTICASONA + SALMETEROL (BR, ROW)	Seretide Diskus®	R03A ADRENERGICS, INHALANTS	Capsules-Powder for Inhalation	500/50 mcg, 250/50mcg, 100/50mcg
FLUTICASONE PROPIONATE (ROW)	Flixotide® Accuhaler	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	Capsules-Powder for Inhalation	500mcg, 250mcg, 100mcg
FORMOTEROL (EU)	Foradil®	R03A ADRENERGICS, INHALANTS	Capsules-Powder for Inhalation	12mcg
TIOTROPIUM BROMIDE METHANOL SOLVATE (EU)	Spiriva® Handihaler	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	Capsules-Powder for Inhalation	10mcg





## HORMONES

NAME	BRAND NAME (REFERENCE)	ATC-INDICATION	PHARMACEUTICAL FORM	DETAILS STRENGTH
CHLORMADINONE 2mg / 0.030mg EE (EU)	Belara®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7 only in LATAM
CHLORMADINONE 2mg / 0.020mg EE (ROW)	BELARINA	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7 only in LATAM
CYPROTERONE 2mg / 0.035mg EE (ROW)	Diane 35®	G03H ANTIANDROGENS	Tablets	21, 21+7
DESOGESTREL 0.075mg (EU)	Cerazette®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	28
DESOGESTREL 0.150mg / 0.020mg EE (EU)	Mercilon®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
DESOGESTREL 0.150mg / 0.030mg EE (EU)	Marvelon®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
DIENOGEST 2MG (EU)	Visanne®	G03D PROGESTOGENS	Tablets	2MG
DIENOGEST 2mg / 0.030mg EE (EU)	Valette®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
DIENOGEST 2mg / 1mg EV (EU)	Climodien® / Lafamme®	G03F PROGESTOGENS AND ESTROGENS IN COMBINATION	Tablets	28
DIENOGEST 2mg / 2mg EV (LATAM)	Climodien® / Lafamme®	G03F PROGESTOGENS AND ESTROGENS IN COMBINATION	Tablets	28
DROSPIRENONE 3mg / 0.020mg EE (EU)	Flexyess®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	120 (Flexible)
DROSPIRENONE 3mg / 0.020mg EE (EU)	Yasminelle®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
DROSPIRENONE 3mg / 0.020mg EE (EU)	Yaz®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	24+4
DROSPIRENONE 3mg / 0.030mg EE (EU)	Yasmin®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
GESTODENE 0.060mg / 0.015mg EE (EU)	Minesse®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	24+4
GESTODENE 0.075mg / 0.020mg EE (EU)	Meliane®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
GESTODENE 0.075mg / 0.030mg EE (EU)	Gynera®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
LEVONORGESTREL 0.100mg / 0.020mg EE (EU)	Leios® / Microgynon® 20	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
LEVONORGESTREL 0.150mg / 0.030mg EE (EU)	Microgynon®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	21, 21+7
LEVONORGESTREL 0.75mg (EU)	Postinor®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	2
LEVONORGESTREL 1.5mg (EU)	Postinor One Step®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	1



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## SOLIDS

PROJECT NAME	BRAND NAME (REFERENCE)	ATC-CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY*
ATORVASTATIN (EU)	Lipitor®	C10A LIPID MODIFYING AGENTS, PLAIN	Film Coated Tablets	10 mg, 20 mg, 40 mg, 80 mg	SUBMITTED - 2Q-17
BARNIDIPINO CLORHIDRATO (EU)	Barnix, Hypoca, Libradin, Vasexten®	C08C SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	Capsules-Pellets	10mg, 20mg	1Q-19
BUDESONIDE (EU)	Entocort Ec®	A07E INTESTINAL ANTIINFLAMMATORY AGENTS	Capsules-Pellets	3mg	4Q-18
CELECOXIB (EU)	Celebrex®	M01A ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS	Capsules-Powder	100mg, 200mg	4Q-17
DABIGATRAN MESYLATE (EU, US)	Pradaxa®	B01A ANTITHROMBOTIC AGENTS	Capsules-Pellets	75mg, 110mg, 150mg	1Q-19
DALFAMPRIDINE (US)	Ampyra®	N07X OTHER NERVOUS SYSTEM DRUGS	Film Coated Tablets	10mg	TBD
DEFERAXIROX (EU)	Exjade® / Jadenu®	V03A ALL OTHER THERAPEUTIC PRODUCTS	Tablets	90mg, 180mg, 360mg	4Q-18
DIMETHYL FUMARATE (EU, ROW)	Tecfidera®	N07X OTHER NERVOUS SYSTEM DRUGS	Capsules-Minitabs	120 mg, 240 mg	TBD
DUTASTERIDE / TAMSULOSINE (EU)	Combodart, Duodart®	G04C DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	Capsules-Pellets	0.5/0.4 mg	SUBMITTED - 2Q-17
ESOMEPRAZOLE (EU)	Nexium Mups®	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Capsules-Pellets	20mg, 40mg	TBD
ETORICOXIB (EU)	Arcoxia®	M01A ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS	Tablets	30mg, 60mg, 90mg, 120mg	TBD
EZETIMIBE (EU)	Zetia®	C10A LIPID MODIFYING AGENTS, PLAIN	Tablets	10mg	SUBMITTED - 4Q-15
EZETIMIBE / ROSUVASTATINA (EU)	Atozet®	C10B LIPID MODIFYING AGENTS, COMBINATIONS	Capsules-Powder	10mg/40 mg, 10mg/20 mg, 10mg/10 mg, 10mg/5 mg	TBD
FAMPRIDINE (EU)	Fampyra®	N07X OTHER NERVOUS SYSTEM DRUGS	Film Coated Tablets	10mg	3Q-18
FEBUXOSTAT	Adenuric® (EU) / Uloric® (US)	M04A ANTIGOUT PREPARATIONS	Film Coated Tablets	80, 120mg	SUBMITTED - 1Q-17
FESOTERODINE (EU)	Toviaz®	G04B UROLOGICALS	Tablets	4mg, 8mg	1Q-19
FINGOLIMOD (EU)	Gylenia®	L04A IMMUNOSUPPRESSANTS	Capsules-Powder	0.5mg	4Q-18
IBUPROFEN (EU)	Nurofen	M01A ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS	Soft Gelatin Capsule	200mg, 400 mg	1Q-18 (MARCH 2018)
LANSOPRAZOL PREMIUM (EU)	Prevacid® / Losec®	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Capsules-Pellets	15mg, 30mg, 60mg	TBD
LENALIDOMIDE (EU)	Revlimid®	L04A IMMUNOSUPPRESSANTS	Capsules-Pellets	2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg	TBD
METHYLPHENIDATE (EU)	Concerta®	N06B PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS	Osmotic tablet	18mg, 27mg, 36mg, 54mg	4Q-18
OMEPRAZOL PREMIUM (EU)	Losec®	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Capsules-Pellets	20mg, 40mg	3Q-18

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## SOLIDS

PROJECT NAME	BRAND NAME (REFERENCE)	ATC-CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY*
PANTOPRAZOL (EU)	Angastra/Pantecta/ Patoloc/Somac®	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Film Coated Tablets	20mg, 40mg	4Q-17
POSACONAZOLE (EU)	Noxafi®	J02AC04 ANTIMYCOTICS FOR SYSTEMIC USE	Film Coated Tablets	100mg	2Q-18
RANOLAZINE (EU)	Ranexa®	C01E OTHER CARDIAC PREPARATIONS	Tablets	375mg, 500mg, 750mg	1Q-18
ROSUVASTATINE (EU)	Crestor®	C10A LIPID MODIFYING AGENTS, PLAIN	Film Coated Tablets	10 mg, 20mg, 40 mg, 80 mg	SUBMITTED - 1Q-17
SILODOSIN (EU)	Silodyx® / Urorec® (EU) Rapaflo® (US)	G04C DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	Capsules-Powder	4mg, 8mg	4Q-17
SITAGLIPTIN (EU)	Januvia®	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	25mg, 50mg, 100mg	1Q-19
SITAGLIPTIN / METFORMIN (EU)	Janumet®	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	50mg/850mg, 50mg/1000mg	1Q-19
TAPENTADOL (EU)	Palexia®	N02A OPIOIDS	Tablets	25mg, 50mg, 100mg, 150mg, 200mg, 250mg	4Q-18

## SEMISOLIDS

PROJECT NAME	BRAND NAME (REFERENCE)	ATC-CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY*
ACYCLOVIR CREAM (ROW)	Zovirax®	D06B CHEMOTHERAPEUTICS FOR TOPICAL USE	Cream	5%	SUBMITTED - 4Q-17
ACYCLOVIR OINTMENT (ROW)	Zovirax®	D06B CHEMOTHERAPEUTICS FOR TOPICAL USE	Ointment	5%	SUBMITTED - 2Q-17
DICLOFENAC SODIUM TOPICAL GEL (ROW)	Voltaren® Gel	M02A TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Gel	1%	4Q-18
ESTRADIOL (US)	Estrace®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Cream	0.01%	TBD
PENTOSAN (EU)	Thrombocid®	C05B ANTIVARICOSE THERAPY	Cream	1mg/g, 5mg/g	1Q-19
PROGESTERONE (EU)	Utrogestan®	G03D PROGESTOGENS	Soft Gelatin Capsule	100mg, 200mg	1Q-19
TESTOSTERONE (EU)	Testogel®	G03B ANDROGENS	Gel	1%	4Q-18
TESTOSTERONE (ROW)	AndroGel®	G03B ANDROGENS	Gel	1.62%	4Q-17



## RESPIRATORY

PROJECT NAME	BRAND NAME (REFERENCE)	ATC-CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY*
GLYCOPYRRONIUM BROMIDE (EU)	Seebri Breezhaler®	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	Capsules-Powder for Inhalation	44mcg	1Q-20
INDACATEROL/ GLYCOPYRRONIUM (EU)	Ultibro Breezhaler®	R03A ADRENERGICS, INHALANTS	Capsules-Powder for Inhalation	85mcg / 43mcg	TBD
TIOTROPIUM SOFT MIST (EU)	Spiriva Respimat®	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	Other	2.5mcg	3Q-20

## HORMONES

PROJECT NAME	BRAND NAME (REFERENCE)	ATC-CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY*
ABIRATERONE (EU)	Zytiga®	L02B HORMONE ANTAGONISTS AND RELATED AGENTS	Film Coated Tablets	500mg	3Q-19
DIENOGEST/EV QUATRIPHASIC (EU)	Qlaira®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	Multiphasic	1Q-19
DYDROGESTERONE (EU)	Duphaston®	G03D PROGESTOGENS	Film Coated Tablets	5mg, 10mg	TBD
DYDROGESTERONE / ESTRADIOL (EU)	Femoston®	G03F PROGESTOGENS AND ESTROGENS IN COMBINATION	Film Coated Tablets	1mg+10mg/1mg, 2mg+10mg/2mg	TBD
ETONOGESTREL+ EE VAGINAL RING (EU)	Nuvaring®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Vaginal Ring	0.120mg / 0.015mg	Available
LEVOTHYROXINE SODIUM (EU)	Levaxin®	H03A THYROID PREPARATIONS	Tablets	25mcg, 50 mcg, 75 mcg, 100 mcg, 125 mcg, 150 mcg, 175 mcg & 200 mcg	TBD
NOMEGESTROL ACETATE / HEMIHYDRATE (EU)	Zoely®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	2.5mg /1.5mg	TBD
ULIPRISTAL (EU)	Esmya®	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	5mg	1Q-18

## INJECTABLES

PROJECT NAME	BRAND NAME (REFERENCE)	ATC-CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY*
ARIPIPIRAZOLE (EU)	Abilify Maintena Kit®	N05A ANTIPSYCHOTICS	Aq. Suspension	300mg, 400mg	2022
BETAMETHASONE ACETATE / SODIUM PHOSPHATE (ROW)	Celestone Soluspan®	H02A CORTICOSTEROIDS	Aq. Suspension	3mg/mL	4Q-18
GLYCOPYRROLATE (ROW)	Robinul®	A03A DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Aq. Solution	0.2mg/mL (1mL, 2mL, 5mL, 20mL)	2Q-18
ICATIBANT (EU)	Firazyr®	B06A OTHER HEMATOLOGICAL AGENTS	Aq. Solution	30mg/3mL (10mg/mL)	3Q-18
PALIPERIDONE PALMITATE (EU)	Xeplion®	N05A ANTIPSYCHOTICS	Aq. Suspension	25mg, 50mg, 75mg, 100mg, 150mg	2021
PALIPERIDONE PALMITATE 3-MONTHLY (EU)	Trevicta®	N05A ANTIPSYCHOTICS	Aq. Suspension	175mg, 263mg, 350mg, 525mg	TBD
SUGAMMADEX (EU)	Bridion®	V03A ALL OTHER THERAPEUTIC PRODUCTS	Aq. Solution	100mg/mL (2mL, 5mL)	2019
TRIAMCINOLONE ACETONIDE (ROW)	Kenalog 10® and Kenalog 40	H02A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN	Aq. Suspension	10mg/mL (5mL) and 40mg/mL (1mL, 5mL, 10mL)	4Q-19

## HORMONAL INJECTABLES

PROJECT NAME	BRAND NAME (REFERENCE)	ATC-CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY*
FULVESTRANT (EU)	Faslodex®	L02BA ANTI-ESTROGENS	Oily Solution	250mg/5mL (50mg/mL)	4Q-18
HYDROXYPROGESTERONE CAPROATE (ROW)	Makena®	G03D PROGESTOGENS	Oily Solution	1250mg/5mL (250mg/mL)	2Q-18
LEVOTHYROXINE (ROW)	Levothyroxine Sodium For Injection®	H03A THYROID PREPARATIONS	Lyo	100mcg, 200mcg, 500mcg	3Q-18
MEDROXYPROGESTERONE ACETATE (EU, ROW)	Depo-Provera®	G03D PROGESTOGENS	Aq. Suspension	150mg/mL	2019
TESTOSTERONE CYPIONATE (ROW)	Depo-Testosterone®	G03B ANDROGENS	Oily Solution	100mg/mL (10mL), 200mg/mL (1mL, 10mL)	4Q-18
TESTOSTERONE UNDECANOATE (ROW)	Aveed®	G03B ANDROGENS	Oily Solution	750mg/3mL (250mg/mL)	TBD



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