

# VADEMECUM

2021 - 2022



CHEMO

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# Experts in the entire pharmaceutical value

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## API PORTFOLIO

<b>Química Sintética</b>	Spain
<b>Industriale Chimica</b>	Italy
<b>Maprimed</b>	Argentina
<b>Nosch Laboratories</b>	India

## API PIPELINE

<b>Química Sintética</b>	Spain
<b>Industriale Chimica</b>	Italy
<b>Maprimed</b>	Argentina
<b>Universal Farma</b>	Spain
<b>Chemo Biosynthesis</b>	Italy
<b>Tyche</b>	India
<b>SMS</b>	India

## FDF PORTFOLIO

<b>Liconsa - Solids</b>	Spain
<b>Liconsa - Semi-solids</b>	Spain
<b>Liconsa - Respiratory</b>	Spain
<b>León Farma - Hormones</b>	Spain

## FDF PIPELINE

<b>Liconsa - Solids</b>	Spain
<b>Liconsa - Semi-solids</b>	Spain
<b>Liconsa - Respiratory</b>	Spain
<b>León Farma - Hormones</b>	Spain
<b>León Farma - Hormonal Semi-solids</b>	Spain
<b>Universal Farma - Injectables</b>	Spain
<b>Farmalan - Hormonal Injectables</b>	Spain
<b>Chemo India Formulations - Solids</b>	India

# Experts in the entire pharmaceutical value

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## **QUÍMICA SINTÉTICA**

Madrid (Spain)

**API**

## **LEÓN FARMA**

Leon (Spain)

**FDF**

## **FARMALAN**

Leon (Spain)

**FDF**

## **UNIVERSAL FARMA**

Guadalajara (Spain)

**FDF**

## **LICONSA**

Guadalajara (Spain)

**FDF**

## **NOSCH LABORATORIES**

Hyderabad (India)

**API**

## **CHEMO INDIA FORMULATIONS**

Hyderabad (India)

**FDF**

## **EXELTIS TURKEY**

Çerkezköy (Turkey)

**FDF**

## **INDUSTRIALE CHIMICA**

Saronno (Italy)

**API**

## **CHEMO BIOSYNTHESIS**

Corana (Italy)

**API**

## **MAPRIMED**

Buenos Aires (Argentina)

**API**

# FDF TECHNOLOGIES

VADEMECUM 2021-2022



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The most advanced, sophisticated technologies for immediate-release and modified-release solids in both tablet and capsule forms.



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One of the world's largest fluid bed (1,300kg/batch)



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Specialized in manufacturing steroids and proton pump inhibitors.



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Equipped to manufacture all hormone products including granules, oral and vaginal tablets, soft capsules, creams and vaginal rings.



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Two injectable plants in Spain.

# Cutting-edge technology and robust industrial capacity

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Chemo's FDF manufacturing sites boast the most advanced, sophisticated technologies for immediate-release and modified-release solids in both tablet and capsule forms. The plants feature 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 world's largest fluid bed batch processors, with a capacity of 1,300 kg per batch.

We are also equipped to manufacture hormonal products, including granules, oral and vaginal tablets, soft capsules, creams and vaginal rings.

In addition, Chemo specialises in manufacturing steroids and proton pump inhibitors.

As part of our reinvestment and continuous improvement programmes, we have two injectable plants in Spain - one of which is dedicated to injectable hormonal products - as well as a plant in India which manufactures oral solid dosage forms. These facilities provide solutions using the latest technology and in accordance with the highest quality standards.

# Cutting-edge technology and robust industrial capacity

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## CHEMO TECHNOLOGIES

Inhalers



Oral solids



Steriles



Hormonal



Semi-solids





## 6 BN

Capsules

## 1.5 M

Pellets (kg)



### 1. Powder-filled capsules

Broad range of sizes and colour combinations.

### 2. Pellet-filled capsules

Broad range of sizes and colour combinations.

### 3. Coated tablets

Including functional coating and aesthetic coating. Immediate and controlled release.



### 4. Bilayer tablets

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

### 5. Matrix tablets

Controlled-release technology.



### 6. Mini-tablet filled capsules

Immediate release or controlled release.

### 7. Osmotic tablets

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



### 8. Soft gelatine capsules

### 9. Oral solutions (PFS)

## 2 BN

Tablets

## 400 M

Soft gel capsules



## 1 BN

Capsules for inhalation

## 4 BN

Tablets



### 10. DPI

Dry Powder Inhalers using monodose capsules.

### 11. SMI

Soft Mist Inhalers generating a high fine particle fraction.

# HORMONAL TECHNOLOGIES

## 8 M

Vaginal rings

## 300 M

Capsules



### 12. Tablets

Oral contraceptives for all regimens, including 21+7, 24+4 and 84+7, among others.

### 13. Chewable tablets

Oral contraceptives: single and fixed-dose combinations.

### 14. Vaginal tablets with applicator



### 15. Vaginal rings

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

### 16. Oral soft gelatine capsules

### 17. Intravaginal soft gelatin capsules

## 30 M

Pre-filled syringes  
Universal Farma

## 45 M

Vials Universal Farma

## 2.5 TONES

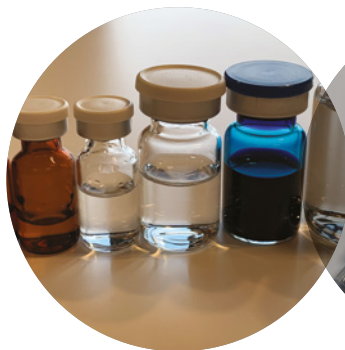
API sterile

## 30 M

Pre-filled syringes Farmalan

## 15 M

Vials Farmalan



18. Aqueous solutions in both glass vials and syringes



19. Oily solutions in both glass vials and syringes



20. Lyophilised vials



21. Aqueous suspensions in both glass vials and syringes (Glass or polymer)

22. API bulk sterilization by sterile filtration and capability to offer Sterile API Micronization in isolator technologies

## 190 M

Semi-solids



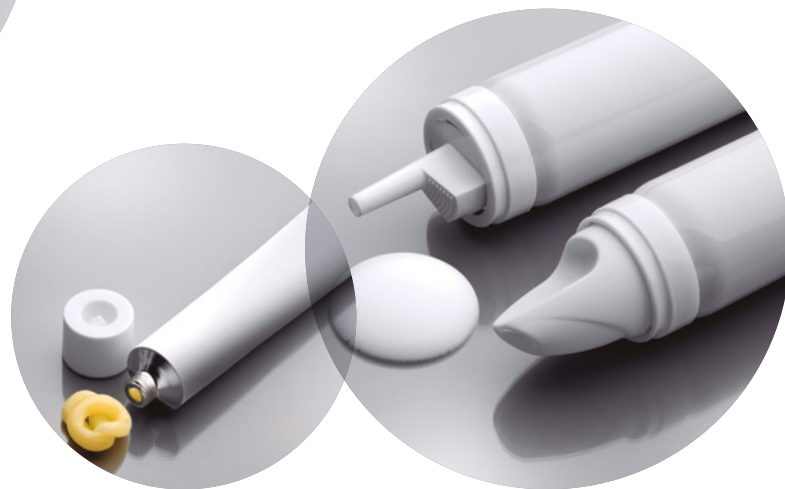
### 23. Gels

Aqueous and oil-based gels.



### 24. Creams.

Emulsions, suspensions, solutions, water in oil (w/o) & oil in water (o/w).



### 25. Ointments

Hydrophilic & hydrophobic ointments.

### 26. Foams

Solution and emulsion formulations.

# PRODUCT LIST

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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.

**SOLIDS**

PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
ARIPIRAZOL EU	Abilify®	CNS	N05A ANTIPSYCHOTICS	Tablet	5MG, 10MG, 15MG, 30MG
ATORVASTATIN EU	Lipitor®	Cardiovascular	C10A LIPID MODIFYING AGENTS, PLAIN	Film-coated tablet	10MG, 20MG, 40MG, 80MG
CANDESARTAN EU	Atacand®	Cardiovascular	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Film-coated tablet	8MG, 16MG, 32MG
CANDESARTAN / HCTZ EU	Atacand Plus®	Cardiovascular	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Tablet	8MG/12.5MG, 16MG/12.5MG, 32MG/12.5MG, 32MG/25MG
CELECOXIB EU	Celebrex®	Analgesics & Anti-Inflammatories	M01A ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS	Capsule, hard	100MG, 200MG
DUTASTERIDE EU	Avodart®	Other Hormone Disorders	G04C DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	Capsule, soft	0,5MG
DUTASTERIDE / TAMSULOSINE EU	Combodart®, Duodart®	Other Hormone Disorders	G04C DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	Capsule, hard	0.5MG/0.4MG
EPLERENONE EU	Inspira®	Cardiovascular	C03D POTASSIUM-SPARING AGENTS	Film-coated tablet	25MG, 50MG
EZETIMIBE EU	Ezetrol®	Cardiovascular	C10A LIPID MODIFYING AGENTS, PLAIN	Tablet	10MG
FEBUXOSTAT EU	Adenuric®	Musculo-skeletal system	M04A ANTIGOUT PREPARATIONS	Film-coated tablet	80MG, 120MG
FLECAINIDE SR EU	Flecaine®	Cardiovascular	C01B ANTIARRHYTHMICS, CLASS I AND III	Prolonged-release capsule, hard	50MG, 100MG, 150MG, 200MG
<b>NEW</b> FOSFOMYCIN RoW	Monurolo®	Anti-Infectives	J01X OTHER ANTIBACTERIALS	Sachets	3G
IBANDRONATE EU	Bonviva®	Musculo-skeletal system	M05B DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	Film-coated tablet	150 MG
IRBESARTAN EU	Karvea®	Cardiovascular	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Tablet	75MG, 150MG, 300MG
IRBESARTAN / HCTZ EU	Co Aprove!®	Cardiovascular	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Tablet	150MG/12.5MG; 300MG/12.5MG, 300MG/25MG
ITRACONAZOLE EU	Sporanox®	Anti-Infectives	J02A ANTIMYCOTICS FOR SYSTEMIC USE	Capsule, hard	100MG
IVABRADINE EU	Procoralan®	Cardiovascular	C01E OTHER CARDIAC PREPARATIONS	Film-coated tablet	5MG, 7.5MG
<b>NEW</b> IVERMECTIN EU	Stromectol®	Anti-Infectives	P02C ANTINEMATODAL AGENTS	Film Coated Tablets	3MG
LANSOPRAZOLE EU	Prezal®, Opiren®	Gastroenterology	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Gastro-resistant capsule, hard	15MG, 30MG
LEVOFLOXACIN RoW	Tavanic®	Anti-Infectives	J01M QUINOLONE ANTIBACTERIALS	Tablet	500MG
LOSARTAN EU	Cozaar®	Cardiovascular	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Film-coated tablet	12.5MG, 25MG,50MG,100MG
LOSARTAN / HCTZ EU	Cozaar Plus®	Cardiovascular	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Film-coated tablet	100/25MG, 100/12.5 MG/, 50/12.5MG

## SOLIDS

	PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
NEW	MIDAZOLAM EU	Hypnovel®/Dormicum®/Buccolam®	Central nervous system	N05C HYPNOTICS AND SEDATIVES	Oral solution	2.5MG, 5MG, 7.5MG, 10MG
	OMEPRAZOL PREMIUM EU	Losec®	Gastroenterology	A02B DRUGS FOR PEPTIC ULCER AND GAS-TRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Gastro-resistant capsule, hard	10MG, 20MG, 40MG
	PREGABALINE EU	Lyrica®	CNS	N03A ANTIEPILEPTICS	Capsule, hard	25MG, 50MG, 75MG, 100MG, 150MG, 200MG, 300MG
	RABEPRAZOLE EU	Pariet®	Gastroenterology	A02B DRUGS FOR PEPTIC ULCER AND GAS-TRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Gastro-resistant tablet	10MG, 20MG
	ROSUVASTATINE EU	Crestor®	Cardiovascular	C10A LIPID MODIFYING AGENTS, PLAIN	Film-coated tablet	5MG, 10MG, 20MG, 40MG
	SILDENAFIL EU	Viagra®	Urology	G04B UROLOGICALS	Film-coated tablet	25MG, 50MG, 100MG
	TELMISARTAN EU	Micardis®	Cardiovascular	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Tablet	20MG, 40MG, 80MG
	TELMISARTAN / HCTZ EU	Micardis® Plus	Cardiovascular	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Film-coated tablet	80MG/25MG, 80MG/12.5MG, 40MG/12.5MG
	TERBINAFINE EU	Lamisil®	Anti-Infectives	D01B ANTIFUNGALS FOR SYSTEMIC USE	Film-coated tablet	250 MG
	TIANEPTINE EU	Stablon®; Coaxil®	CNS	N06A ANTIDEPRESSANTS	Film-coated tablet	12.5MG
	VALSARTAN EU	Diovan®	Cardiovascular	C09C ANGIOTENSIN II ANTAGONISTS, PLAIN	Film-coated tablet	40 MG, 80MG, 160MG, 320MG
	VALSARTAN / HCTZ EU	Co Diovan®	Cardiovascular	C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	Film-coated tablet	80/12.5MG, 160/12.5MG, 160/25MG
	VENLAFAXINE EU	Effexor®	CNS	N06A ANTIDEPRESSANTS	Prolonged-release tablet	37.5MG, 75MG, 150MG, 225 MG, 300 MG

## SEMISOLIDS

	PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
	ACYCLOVIR RoW	Zovirax®	Anti-Infectives	D06B CHEMOTHERAPEUTICS FOR TOPICAL USE	Cream	5%
	ACYCLOVIR RoW	Zovirax®	Anti-Infectives	D06B CHEMOTHERAPEUTICS FOR TOPICAL USE	Ointment	5%
	CLOBETASOL RoW	Clobetasol Propionate Cream®	Analgesics & Anti-Inflammatories	D07A CORTICOSTEROIDS, PLAIN	Cream	0.05%

## SEMISOLIDS

PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
CLOBETASOL RoW	Temovate®	Analgesics & Anti-Inflammatories	D07A CORTICOSTEROIDS, PLAIN	Ointment	0.05%
LACTIC ACID II EU	Geliofil®	Other Hormone Disorders	G01A ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS	Vaginal gel	n/a (7 X 5ML)
TERBINAFINE EU	Lamisil®	Anti-Infectives	D01A ANTIFUNGALS FOR TOPICAL USE	Cream	1%

## RESPIRATORY

PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
BUDESONIDE / FORMOTE-ROL BR	Foraseq®	Respiratory	R03AK ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS	Inhalation powder, hard capsule	400MCG /12MCG
FLUTICASONA / SALMETEROL RoW	Seretide Diskus®	Respiratory	R03A ADRENERGICS, INHALANTS	Inhalation powder, hard capsule	500/50MCG, 250/50MCG, 100/50MCG
FLUTICASONONE PROPIONATE RoW	Flixotide® Accuhaler	Respiratory	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	Inhalation powder, hard capsule	500MCG, 250MCG, 100MCG
FORMOTEROL EU	Foradil®	Respiratory	R03A ADRENERGICS, INHALANTS	Inhalation powder, hard capsule	12MCG
TIOTROPIUM BROMIDE METHANOL SOLVATE EU	Spiriva Handihaler®	Respiratory	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	Inhalation powder, hard capsule	10MCG

## HORMONS

PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
CHLORMADINONE / EE RoW	Belarina®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	2MG / 0.020MG (21, 21+7, 24+4)
CHLORMADINONE / EE EU	Belara®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	2MG / 0.030MG (21, 21+7)
CYPROTERONE / EE RoW	Diane 35®	Hormonal - Contraceptive	G03H ANTIANDROGENS	Film-coated tablet	2MG / 0.035MG (21, 21+7)



**HORMONS**

PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
DESOGESTREL EU	Cerazette®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	0.075MG (28)
DESOGESTREL / EE EU	Mercilon®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	0.150MG / 0.020MG (21, 21+7)
DESOGESTREL / EE EU	Marvelon®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	0.150MG / 0.030MG (21, 21+7)
DIENOGEST EU	Visanne®	Other Hormone Disorders	G03D PROGESTOGENS	Tablet	2MG
DIENOGEST / EE EU	Valette®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	2MG / 0.030MG (21, 21+7)
DIENOGEST / EV EU	Lafamme®	Hormonal - Contraceptive	G03F PROGESTOGENS AND ESTROGENS IN COMBINATION	Film-coated tablet	2MG / 1MG (28)
DIENOGEST / EV RoW	Climodien®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	2MG / 2MG (28)
DROSPIRENONE / EE EU	Yasminelle®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	3MG / 0.020MG (21, 21+7)
DROSPIRENONE / EE EU	Yaz®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	3MG / 0.020MG (24+4)
DROSPIRENONE / EE EU	Yasmin®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	3MG / 0.030MG (21, 21+7)
DROSPIRENONE / EE (FLEXIBLE) EU	Flexyess®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	3MG / 0.020MG (120 - Flexible)
ETONOGESTREL / EE EU	Nuvaring	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Vaginal delivery system	0.120MG / 0.015MG (daily)
GESTODENE / EE EU	Minesse®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	0.060MG / 0.015MG (24+4)
GESTODENE / EE EU	Meliane®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablet	0.075MG / 0.020MG (21, 21+7)
GESTODENE / EE EU	Gynera®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablet	0.075MG / 0.030MG (21, 21+7)
LEVONORGESTREL EU	Postinor®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablet	0.75MG (2)
LEVONORGESTREL EU	Postinor One Step®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablet	1.5MG (1)
LEVONORGESTREL / EE EU	Leios® / Microgynon® 20	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	0.100MG / 0.020MG (21, 21+7)

## HORMONS

PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
LEVONORGESTREL / EE EU	Microgynon®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film-coated tablet	0.150MG / 0.030MG (21, 21+7)
PROGESTERONE EU	Utrogestan®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Capsule, Soft	100MG, 200MG
ULIPRISTAL EU	Esmya®	Other Hormone Disorders	G03X OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	Film Coated Tablets	5MG

## HORMONAL INJECTABLES

PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
FULVESTRANT EU	Faslodex®	Other Hormone Disorders	L02BA ANTI-ESTROGENS	Oily Solution - PFS	250MG/5ML (50MG/ML)
<b>NEW</b> MEDROXYPROGESTERONE ACETATE RoW	Depo-Provera®	Hormonal - Contraceptive	G03D PROGESTOGENS	Aq. Suspension - vials	150MG/ML (1ML)
<b>NEW</b> MEDROXYPROGESTERONE ACETATE RoW	Depo-Provera®	Hormonal - Contraceptive	G03D PROGESTOGENS	Aq. Suspension - PFS	150MG/ML (1ML)
<b>NEW</b> NORETHISTERONE ENANTHATE + ESTRADIOL VALERATE RoW	Mesigyna®	Hormonal - Contraceptive	G03F PROGESTOGENS AND ESTROGENS IN COMBINATION	Oily Solution - vials / PFS	50mg/5mg (1mL)

## INJECTABLES

PRODUCT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC INDICATION	FARMACEUTICAL FORM	DETAILS STRENGTH
<b>NEW</b> CYANOCOBALAMIN RoW	Vibisone® (Discontinued). Using Rs Luitpold And Mylan For Development	Other Therapies	B03B VITAMIN B12 AND FOLIC ACID	Aq. Solution - vials	1mg/mL (1mL and 30mL)
<b>NEW</b> GLYCOPYRROLATE RoW	Robinul®	Other Therapies	A03A DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Aq. Solution - vials	0.2mg/mL (1mL, 2mL, 5mL, 20mL)
<b>NEW</b> TESTOSTERONE RoW	Androgel®	Other Hormone Disorders	G03B ANDROGENS	Gel - pumps	1,62%

## SOLIDS

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
APIXABAN EU	Eliquis®	Other Therapies	B01A ANTITHROMBOTIC AGENTS	Film Coated Tablets	2.5mg & 5mg	TBD
ARIPIPRAZOL EU	Abilify®	Central nervous system	N05A ANTIPSYCHOTICS	Tablets	20mg	1Q-22
ATORVASTATIN / EZE-TIMIBE EU	Atozet®	Cardiovascular	C10B LIPID MODIFYING AGENTS, COMBINATIONS	Film Coated Tablets	40mg/10mg; 20mg/10mg; 80mg/10mg	3Q-22
ATORVASTATIN EU	Lipitor®	Cardiovascular	C10A LIPID MODIFYING AGENTS, PLAIN	Film Coated Tablets	30mg, 60mg	READY
BARNIDIPINO CLORHIDRATO EU	Barnix®, Hypoca®, Libradin®, Vasexten®	Cardiovascular	C08C SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	Capsules-Pellets	10mg, 20mg	2Q-22
BUDESONIDE EU	Entocort Ec®	Gastroenterology	A07E INTESTINAL ANTIINFLAMMATORY AGENTS	Capsules-Pellets	3mg	READY
DABIGATRAN MESYLATE EU	Pradaxa®	Cardiovascular	B01A ANTITHROMBOTIC AGENTS	Capsules-Pellets	75mg, 110mg, 150mg	READY
DAPAGLIFLOZIN / MET-FORMIN EU	Ebymect®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	5mg/850mg, 5mg/1000 mg	TBD
DAPAGLIFLOZIN EU	Edistride®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	5mg, 10mg	TBD
DIMETHYL FUMARATE EU	Tecfidera®	Central nervous system	N07X OTHER NERVOUS SYSTEM DRUGS	Capsules-Minitabs	120 mg, 240 mg	3Q-22
DULOXETINE EU	Cymbalta®	Central nervous system	N06A ANTIDEPRESSANTS	Capsules-Pellets	30mg, 60mg	READY
DULOXETINE EU	Cymbalta®	Central nervous system	N06A ANTIDEPRESSANTS	Capsules-Pellets	90mg, 120mg	READY
EDOXABAN EU	Lixiana®	Other Therapies	B01A ANTITHROMBOTIC AGENTS	Film Coated Tablets	15mg, 30mg, 60mg	TBD
ELTROMBOPAG EU	Revolade®	Cardiovascular	B02B VITAMIN K AND OTHER HEMOSTATICS	Film Coated Tablets	12.5mg, 25mg, 50mg, 75mg	TBD
ESOMEPRAZOLE EU	Nexium®	Gastroenterology	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Tablets-pellets	20mg, 40mg	4Q-22
ESOMEPRAZOLE EU	Nexium®	Gastroenterology	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Capsules-Pellets	20mg, 40mg	2Q-22
ESOMEPRAZOLE RoW	Nexium®	Gastroenterology	A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Tablets-pellets	20mg, 40mg	2Q-22
FAMPRIDINE EU	Fampyra®	Central nervous system	N07X OTHER NERVOUS SYSTEM DRUGS	Film Coated Tablets	10mg	READY
FERRIC CITRATE RoW	Auryxia®	Other Therapies	V03A ALL OTHER THERAPEUTIC PRODUCTS	Tablets	EQ 210mg Iron	3Q-22
FESOTERODINE EU	Toviaz®	Urology	G04B UROLOGICALS	Tablets	4mg, 8mg	READY
FINGOLIMOD EU	Gylenia®	Other Therapies	L04A IMMUNOSUPPRESSANTS	Capsules-Powder	0,5mg	READY

## SOLIDS

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
IVACAFTOR EU	Kalydeco®	Other Therapies	R07A OTHER RESPIRATORY SYSTEM PRODUCTS	Film Coated Tablets	150mg	TBD
LANSOPRAZOL PREMIUM EU	Opiren®	Gastroenterology	A02B DRUGS FOR PEPTIC ULCER AND GAS-TRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Capsules-Pellets	15mg, 30mg	TBD
LINAGLIPTIN EU	Trajenta®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	5mg	TBD
LISDEXAMFETAMINE EU	Vyvanse®	Central nervous system	N06BA12 - LISDEXANFETAMINA	Capsules	20mg, 30mg, 40mg, 50mg, 60mg, 70mg	TBD
LURASIDONE EU	Latuda®	Schizophrenia	N05A ANTIPSYCHOTICS	Tablets	20mg, 40mg, 60mg, 80mg and 120mg	2Q-22
METHYLPHENIDATE EU	Concerta®	Central nervous system	N06B PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS	Osmotic tablet	18mg, 27mg, 36mg, 54mg	READY
OXYBUTYNIN EU	Lyrinel XL®	Urology	G04B UROLOGICALS	Osmotic tablet	5mg, and 10mg	2Q-22
PANTOPRAZOL EU	Angastra®/Pantec-ta®/Patoloc®/Somac®	Gastroenterology	A02B DRUGS FOR PEPTIC ULCER AND GAS-TRO-OESOPHAGEAL REFLUX DISEASE (GORD)	Film Coated Tablets	20mg, 40mg	1Q-22
PERAMPANEL EU	Fycompa®	Central nervous system	N03A ANTIEPILEPTICS	Film Coated Tablets	10mg, 12mg, 2mg, 4mg, 6mg, 8mg	TBD
PIRFENIDONE EU	Esbriet®	Respiratory	L04A IMMUNOSUPPRESSANTS	Tablets	267mg, 534mg and 801mg	READY
PREGABALINE EU	Lyrica®	Central nervous system	N03A ANTIEPILEPTICS	Capsules	225mg	4Q-21
RANOLAZINE EU	Ranexa®	Cardiovascular	C01E OTHER CARDIAC PREPARATIONS	Film Coated Tablets	375mg, 500mg, 750mg	2Q-22
RIFAXIMINE EU	Normix®	Anti-Infectives	A07A INTESTINAL	Film Coated Tablets	200mg	3Q-22
RIFAXIMINE EU	Xifaxan®	Anti-Infectives	A07A INTESTINAL	Film Coated Tablets	550mg	TBD
RIVAROXABAN EU	Xarelto®	Cardiovascular	B01A ANTITHROMBOTIC AGENTS	Film Coated Tablets	2.5mg, 10mg, 15mg, 20mg	1Q-22
SAXAGLIPTIN EU	Onglyza®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	2.5mg, 5mg	TBD
SAXAGLIPTIN/ METFORM-IN EU	Komboglyze®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	2.5mg/1g, 2.5mg/800mg	TBD
SELEXIPAG EU	Upravi®	Respiratory	B01A ANTITHROMBOTIC AGENTS	Film Coated Tablets	0.2mg, 0.4mg, 0.6mg, 0.8mg, 1.0mg, 1.2mg, 1.4mg and 1.6mg	1Q-23
SERTRALINE EU	Zoloft®	Central nervous system	N06A - ANTIDEPRESSANTS	Film Coated Tablets	25mg, 50mg, 100mg, 150mg and 200mg	3Q-22

## SOLIDS

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
SITAGLIPTIN / METFORMIN EU	Janumet®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	50 mg/850 mg, 50 mg/ 1000 mg	READY
SITAGLIPTIN / METFORMIN EU, CH	Janumet® / Glucophage®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	50mg/500mg	READY
SITAGLIPTIN EU	Januvia®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Film Coated Tablets	25mg, 50mg, 100mg	READY
TAMSULOSIN EU	Omnice®	Urology	G04C DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	Capsules-Pellets	0,4mg	1Q-23
TAPENTADOL EU	Palexia Er®	Analgesics & Anti-Inflammatories	N02A OPIOIDS	Film Coated Tablets	25 mg, 50mg, 100mg, 150mg, 200mg, 250mg	READY
TERIFLUNOMIDE EU	Aubagio®	Multiple sclerosis	L04AA - SELECTIVE IMMUNOSUPPRESSANTS	Film Coated Tablets	7mg	1Q-22
TICAGRELOR EU	Brilique®	Cardiovascular	B01A ANTITHROMBOTIC AGENTS	Film Coated Tablets	60mg, 90mg	3Q-22
TOFACITINIB EU	Xeljanz®	Other Therapies	M1C (SEP ANTIRHEUMATIC AGENT)	Tablets	5mg, 10mg	TBD
TOFACITINIB EU	Xeljanz® XR	Other Therapies	M1C (SEP ANTIRHEUMATIC AGENT)	Tablets	11mg, 22mg	TBD
VELAFAXINE EU	Effexor®	Central nervous system	N06A - ANTIDEPRESSANTS	Capsules	37.5mg, 75mg, 150mg and 225mg	TBD

## SEMISOLIDS

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
CARBIDOPA / LEVODOPA EU	Duodopa® Gel	Advanced levodopa-responsive Parkinson's disease	N04B DOPAMINERGIC AGENTS	Gel	5mg/20mg per ml (100ml)	2Q-23
IVERMECTIN LOTION 0,5% EU	N/A	Pediculosis capitis (Head Lice Infestation)	D11AX OTHER DERMATOLOGICALS	Lotion	0,5%	2Q-22

## RESPIRATORY

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
GLYCOPYRRONIUM BRO-MIDE EU	Seebri Breezhaler®	Respiratory	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	Capsules-Powder for Inhalation	44mcg	3Q-22
INDACATEROL/GLYCOPIR- RONIUM EU	Ultibro Breezhaler®	Respiratory	R03A ADRENERGICS, INHALANTS	Capsules-Powder for Inhalation	85mcg / 43 mcg	2Q-23
SUMATRIPTAN EU	Imigran®	Analgesics & Anti-Inflam- matories	N02C ANTIMIGRAINE PREPARATIONS	Nasal spray	10mg and 20mg	2Q-23
TIOTROPIUM EU	Spiriva Respimat®	Respiratory	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	Other	1.25mcg, 2.5mcg	2Q-23
ZOLMITRIPTAN EU	Zomig®	Analgesics & Anti-Inflam- matories	N02C ANTIMIGRAINE PREPARATIONS	Nasal spray	2.5mg and 5mg	2Q-23

## INJECTABLES

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
ARIPIPRAZOLE EU	Abilify Maintena Kit®	Central nervous system	N05A ANTIPSYCHOTICS	Aq. Suspension - Lyo - vials	300mg, 400mg	1Q-24
BETAMETHASONE ACETATE AND SODIUM PHOSPHATE RoW	Celestone Soluspan®	Analgesics & Anti-Inflam- matories	H02A CORTICOSTEROIDS FOR SYS- TEMIC USE, PLAIN	Aq. Suspension - vials	3mg/mL + 3mg/mL (5mL)	3Q-22
FERRIC CARBOXYMALT- OSE EU	Ferinject®	Other Therapies	B03A IRON PREPARATIONS	i.v.-Solution - vials	50mg iron/mL (2mL, 10mL, 20mL)	1Q-23
HYDROXOCOBALAMIN, PYRIDOXINE AND THIA- MINE INJECTION LATAM	Bedoyecta Tri®	Other Therapies	B03B VITAMIN B12 AND FOLIC ACID	Aq. Solution - vials	10.000 mcg + 50mg + 100mg / 2mL	3Q-22
ICATIBANT EU	Firazyr®	Cardiovascular	B06A OTHER HEMATOLOGICAL AGENTS	Aq. Solution - PFS	10mg/mL (3mL)	READY
LIRAGLUTIDE EU	Victoza®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Aq. Solution - cartridges	6mg/mL (3mL)	TBD
LIRAGLUTIDE EU	Saxenda®	Endocrinology	A10B BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	Aq. Solution - cartridges	6mg/mL (3mL)	TBD
PALIPERIDONE PALMITATE 3-MONTHLY EU	Trevicta®	Central nervous system	N05A ANTIPSYCHOTICS	Aq. Suspension - PFS	175 mg, 263 mg, 350 mg y 525 mg (paliperidone base)	2026
PALIPERIDONE PALMI- TATE EU	Xeplion®	Central nervous system	N05A ANTIPSYCHOTICS	Aq. Suspension - PFS	25 mg, 50 mg, 75 mg, 100 mg, 150 mg (paliperidone base)	4Q-22

## INJECTABLES

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
TRIAMCINOLONE ACE-TONIDE RoW	Kenalog 40®	Analgesics & Anti-Inflammatories	H02A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN	Aq. Suspension - vials	40mg/mL (1mL, 5mL, 10mL)	READY

## HORMONS

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
ABIRATERONE EU	Zytiga®	Other Hormone Disorders	L02B HORMONE ANTAGONISTS AND RELATED AGENTS	Film Coated Tablets	500mg	READY
DIENOGEST/EV QUAT-RIPHASIC BR	Qlaira®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	3mg + 2mg/2mg + 3mg/2mg + 1mg + Placebo (2+5+17+2+2)	TBD
DIENOGEST/EV QUAT-RIPHASIC EU	Qlaira®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	3mg + 2mg/2mg + 3mg/2mg + 1mg + Placebo (2+5+17+2+2)	1Q-23
DROSPIRENONE/ ESTETROL EU	Nexstellis®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	3MG / 15MG	4Q-23
DROSPIRENONE/EE/LM-F+LMF RoW	Beyaz®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	3mg/0,02mg/0,45mg +0,45	4Q-21
DROSPIRENONE/EE/LM-F+LMF RoW	Safyral®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	3mg/0,03mg/0,45mg +0,45	4Q-21
DUTASTERIDE TABLETS EU	n/a	Other Therapies	G04C DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	Tablet	0,5mg	1Q-22
DIHYDROGESTERONE / ESTRADIOL EU	Femoston®	Other Hormone Disorders	G03F PROGESTOGENS AND ESTROGENS IN COMBINATION	Film Coated Tablets	10mg/1mg, 10mg/2mg	TBD
DIHYDROGESTERONE EU	Duphaston®	Other Hormone Disorders	G03D PROGESTOGENS	Film Coated Tablets	10mg	TBD
ESTRETOL EU	Donesta®	Other Hormone Disorders	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Tablets	15mg	TBD
ETONOGESTREL RoW	Nexplanon®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Subdermal Implant	68mg	2Q-22
ULIPRISTAL EU	Ella One®	Hormonal - Contraceptive	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	Film Coated Tablets	30 mg	4Q-22



## HORMONAL INJECTABLES

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
CETRORELIX ACETATE RoW	Cetrotide®	Endocrinology	H01C HYPOTHALAMIC HORMONES	Aq. Solution - Lyo - vials	0.25mg	3Q-22
ESTRADIOL VALERATE RoW	Delestrogen®	Other Hormone Disorders	G03C0 OESTROG EX G3A,G3E,G3F	Oily Solution - Vials	10 mg/ml, 20 mg/ml, 40 mg/ml (5mL)	READY
HYDROXYPROGESTERONE CAPROATE RoW	Makena®	Other Hormone Disorders	G03D PROGESTOGENS	Oily Solution - vials / PFS	250mg/mL (1mL)	READY
MEDROXYPROGESTERONE ACETATE RoW	Depo-Provera®	Hormonal - Contraceptive	G03D PROGESTOGENS	Aq. Suspension - Vials / PFS	150mg/mL (1mL)	READY
NORETHISTERONE ENANTHATE + ESTRADIOL VALERATE RoW	Mesigyna®	Hormonal - Contraceptive	G03F PROGESTOGENS AND ESTROGENS IN COMBINATION	Oily Solution - vials / PFS	50mg/5mg (1mL)	READY
PROGESTERONE EU	Prolutex®	Other Hormone Disorders	G03D PROGESTOGENS	Aq. Solution - vials	25mg/mL (1mL)	4Q-22
PROGESTERONE RoW	Progesterone Injection USP	Other Hormone Disorders	G03D PROGESTOGENS	Oily Solution - vials	50mg/mL (10mL)	READY
TESTOSTERONE CYPIONATE RoW	Depo-Testosterone®	Other Hormone Disorders	G03B ANDROGENS	Oily Solution - vials	100mg/mL (10mL), 200mg/mL (1mL, 10mL)	READY
TESTOSTERONE UNDECANOATE EU	Nebido®	Other Hormone Disorders	G03B ANDROGENS	Oily Solution -vials	750mg/3mL and 1000mg/4mL (250mg/mL)	4Q-21

## HORMONAL SEMISOLIDS

PROJECT NAME / TERRITORY	BRAND NAME (REF.)	THERAPEUTICAL GROUP	ATC CODE	PHARMACEUTICAL FORM	DETAILS STRENGTH	DOSSIER READY
ESTRADIOL / PROGESTERONE US	Bijuva®	Hormonal - Contraceptive	G03F PROGESTOGENS AND ESTROGENS IN COMBINATION	Capsule, Soft	1mg/100mg	3Q-22
TESTOSTERONE EU	Testogel®	Other Hormone Disorders	G03B ANDROGENS	Gel - Pumps	1,62% & 3,24%	4Q-22

## QUÍMICA SINTÉTICA (QS) Spain

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Anti-Infectives	ACYCLOVIR	Viral Infection	CEP/DMF
CNS	ASENAPINE MALEATE	Schizophrenia	DMF
Anti-Infectives	AZITHROMYCIN	Bacterial 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
Analgesics & Anti-Inflammatories	CELECOXIB	Arthritis, Osteoarthritis, Rheumatoid Arthritis	CEP/DMF
Anti-Infectives	CHLORAMPHENICOL	Bacterial Infection	DMF
Anti-Infectives	CIPROFLOXACIN	Bacterial Infection	CEP/DMF
Anti-Infectives	CIPROFLOXACIN HYDROCHLORIDE	Bacterial Infection	CEP/DMF
Gastroenterology	FAMOTIDINE	Peptic Ulcer	DMF
Other Therapies	FEBUXOSTAT	Gout	DMF
Cardiovascular	FLECAINIDE ACETATE	Arrhythmia	CEP/DMF
Anti-Infectives	FLUCONAZOLE	Fungal Infection	CEP/DMF
Cardiovascular	FLUNARIZINE	Migraine, Vertigo	DMF
CNS	FLUOXETINE HYDROCHLORIDE	Depression	DMF
Anti-Infectives	FOSFOMYCIN TROMETHAMINE	Bacterial Infection	CEP/DMF
Cardiovascular	GUANFACINE HYDROCHLORIDE	Hypertension	DMF
Cardiovascular	INDAPAMIDE	Hypertension & Fluid Retention (edema)	CEP filed/DMF
Cardiovascular	IRBESARTAN	Hypertension	DMF
Cardiovascular	ISRADIPINE	Hypertension	DMF
Anti-Infectives	ITRACONAZOLE	Fungal Infection	CEP/DMF
Cardiovascular	IVABRADINE	Acute Coronary Syndrome	DMF
Anti-Infectives	KETOCONAZOLE	Fungal Infection	DMF
Analgesics & Anti-Inflammatories	KETOROLAC TROMETHAMINE	Acute Pain	DMF
Gastroenterology	LANSOPRAZOLE	Peptic Ulcer	CEP/DMF
Anti-Infectives	LEVOFLOXACIN	Bacterial Infection	CEP/DMF
CNS	LEVOMILNACIPRAN	Depression	DMF

## QUÍMICA SINTÉTICA (QS) Spain

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Respiratory	LORATADINE	Allergy Symptoms	CEP/DMF
Cardiovascular	LOSARTAN POTASSIUM	Hypertension	DMF
Analgesics & Anti-Inflammatories	MELOXICAM	Arthritis, Osteoarthritis, Rheumatoid Arthritis	DMF
Anti-Infectives	MICONAZOLE NITRATE	Fungal Infection	CEP/DMF
Respiratory & Ophthalmologicals	NEDOCROMIL SODIUM	Asthma & Ophthalmologicals	DMF
Ophthalmologicals	OFLOXACIN	Eye Bacterial Infection	CEP/DMF
Gastroenterology	OMEPRAZOLE	Peptic Ulcer	CEP/DMF
Gastroenterology	PANTOPRAZOLE SODIUM	Peptic Ulcer	CEP/DMF
Cardiovascular	PERINDOPRIL TERT-BUTYLAMINE	Hypertension	DMF
Veterinarian	PRAZICUANTEL	Antiparasitic Agent	CEP/DMF
Gastroenterology	RABEPRAZOLE SODIUM	Peptic Ulcer	CEP/DMF
Gastroenterology	RANITIDINE	Peptic Ulcer	DMF
CNS	SUMATRIPTAN BASE	Migraine	DMF
CNS	SUMATRIPTAN SUCCINATE	Migraine	CEP/DMF
Other Hormone Disorders	TAMSULOSIN HYDROCHLORIDE	Benign Prostatic Hyperplasia	CEP/DMF
CNS	TASIMELTEON	Non 24-Hour Sleep-Wake Disorder	DMF
Anti-Infectives	TELAPREVIR	Viral Infection	DMF
Cardiovascular	TELMISARTAN	Hypertension	DMF
Anti-Infectives	TERBINAFINE HYDROCHLORIDE	Fungal Infection	CEP/DMF
Anti-Infectives	TERCONAZOLE	Fungal Infection	DMF
CNS	TIANEPTINE SODIUM	Depression	CEP/DMF
Respiratory Veterinary	TULATHROMYCIN	Bovine respiratory disease	DMF
Cardiovascular	VALSARTAN	Hypertension	DMF
CNS	VENLAFAXINE HYDROCHLORIDE	Depression	CEP

## INDUSTRIALE CHIMICA (IC) Italy

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Other Hormone Disorders	ABIRATERONE ACETATE	Prostate Cancer	DMF
Cardiovascular	ALPROSTADIL	Erectile Dysfunction	DMF

## INDUSTRIALE CHIMICA (IC) Italy

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Veterinarian	ALTRENOGEST	Contraceptive	DMF/VMF
Respiratory	BECLOMETHASONE ANHYDROUS	COPD & Asthma	CEP/DMF
Respiratory	BECLOMETHASONE MONOHYDRATE	COPD & Asthma	CEP filed/DMF
Ophthalmologicals	BIMATOPROST	Glaucoma	DMF
Ophthalmologicals	BRINZOLAMIDE	Glaucoma	DMF
Respiratory & Digestive System	BUDESONIDE	Asthma & Crohn disease	CEP/DMF
Cardiovascular	BUMETANIDE	Fluid Retention (edema)	CEP/DMF
CNS	DALFAMPRIDINE	Multiple Sclerosis	DMF
Hormonal - Contraceptive	DESOGESTREL	Contraception	CEP/DMF
Hormonal - Contraceptive	DIENOGEST	Contraception	CEP/DMF
Veterinarian	DL-CLOPROSTENOL	Contraceptive	VMF
Cardiovascular	DOFETILIDE	Arrhythmia	DMF
Hormonal - Contraceptive	DROSPIRENONE	Contraception	CEP/DMF
Cardiovascular	EPLERENONE	Hypertension, Chronic Heart Failure	CEP/DMF
Hormonal - Contraceptive	ETHINYL ESTRADIOL	Contraception	CEP/DMF
Hormonal - Contraceptive	ETONOGESTREL	Contraception	DMF
Respiratory	FENOTEROL	Asthma & COPD	DMF
Respiratory	FLUTICASONE PROPIONATE	Asthma	CEP/DMF
Respiratory	FORMOTEROL FUMARATE	Asthma & COPD	CEP/DMF
Other Hormone Disorders	FULVESTRANT	Breast Cancer	CEP/DMF
Hormonal - Contraceptive	GESTODENE	Contraception	CEP/DMF
CNS	IDEBENONE	Nootropic	DMF
Cardiovascular	INDAPAMIDE	Hypertension & Diuretic	CEP/DMF
Ophthalmologicals	LATANOPROST	Glaucoma	CEP filed/DMF
Hormonal - Contraceptive	LEVONORGESTREL	Contraception	CEP/DMF
Hormonal - Contraceptive	LEVONORGESTREL BUTANOATE	Contraception	DMF
Ophthalmologicals	LOTEPREDNOL ETABONATE	Eye swelling	DMF
CNS	MEMANTINE HYDROCHLORIDE	Alzheimer	DMF
Cardiovascular	MIDODRINE	Hypotension	DMF
Respiratory	MOMETASONE FUROATE ANHYDROUS	Asthma	CEP filed/DMF

## INDUSTRIALE CHIMICA (IC) Italy

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Respiratory	MOMETASONE FUROATE MONOHYDRATE	Asthma	DMF
Hormonal - Contraceptive	NOMEGESTROL	Contraception	CEP/DMF
Hormonal - Contraceptive	NORGESTIMATE	Contraception	CEP/DMF
Cardiovascular	PHENTOLAMINE MESYLATE	Hypertension	CEP/DMF
Respiratory	SALMETEROL XINAFOATE	COPD	CEP/DMF
Ophthalmologicals	SULFAMETHYLTHIAZOL	Ophthalmologicals	DMF
Ophthalmologicals	TAFLUPROST	Glaucoma	DMF
Other Hormone Disorders	TIBOLONE	Hormone Replacement Therapy	CEP/DMF
Respiratory	TIOTROPIUM MONOHYDRATE	Asthma & COPD	CEP/DMF
Respiratory	TIOTROPIUM SOLVATE	Asthma & COPD	DMF
Ophthalmologicals	TRAVOPROST	Glaucoma	DMF
Hormonal - Contraceptive	TRIMEGESTONE	Contraception	DMF
CNS	ZOPICLONE	Sedative & Hypnotic	CEP/DMF

## MAPRIMED (MAP) Argentina

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
CNS	ARIPIRAZOLE	Schizophrenia	DMF
Ophthalmologicals	BIMATOPROST	Glaucoma	DMF
CNS	CARIPRAZINE	Schizophrenia	DMF
Analgesics & Anti-Inflammatories	LYSINE CLONIXINATE	Acute Pain	DMF
CNS	CLOXAZOLAM	Sedative, Hypnotic & Anxiolytic	DMF
Cardiovascular	ENALAPRIL MALEATE	Hypertension	DMF
CNS	ESZOPICLONE	Sedative & Hypnotic	DMF
CNS	FINGOLIMOD HYDROCHLORIDE	Multiple Sclerosis	CEP/DMF
Cardiovascular	FLECAINIDE ACETATE	Arrhythmia	CEP/DMF
Other Therapies	IBANDRONATE SODIUM	Osteoporosis	DMF
Cardiovascular	IVABRADINE HYDROCHLORIDE	Acute Coronary Syndrome	DMF
CNS	LACOSAMIDE	Epilepsy	DMF

**MAPRIMED (MAP)** Argentina

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Anti-rheumatic	LEFLUNOMIDE HYDROCHLORIDE	Arthritis, Rheumatoid Arthritis	CEP/DMF
Endocrinology	LORCASERINE	Obesity	DMF
Cardiovascular	LOSARTAN POTASSIUM	Hypertension	DMF
Human & Veterinarian	NITAZOXANIDE	Antiparasitic Agent	DMF
Cardiovascular	PRASUGREL HYDROCHLORIDE	Acute Coronary Syndrome	DMF
Gastrointestinal	PROPINOX	Antispasmodic	DMF
CNS	RASAGILINE MESYLATE	Parkinson	DMF
Urology	SILDENAFIL CITRATE	Erectile Dysfunction Agent	DMF
CNS	TERIFLUNOMIDE	Treatment of multiple sclerosis	DMF
Respiratory	TIOTROPIUM SOLVATE	Asthma & COPD	DMF
Other Therapies	ZOLEDRONIC ACID MONOHYDRATE	Osteoporosis	CEP filed/DMF

**NOSCH LABORATORIES (NL)** India

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Cardiovascular	ALISKIREN HEMIFUMARATE	Hypertension	DMF
CNS	ALMOTRIPTAN MALATE	Migraine	DMF
Anti-Infectives	AMOROLFINE HYDROCHLORIDE	Antifungal	DMF
Cardiovascular	DABIGATRAN	Anticoagulant	DMF
Urology	DAPOXETINE HYDROCHLORIDE	Premature Ejaculation	DMF
Gastroenterology	DEXLANSOPRAZOLE	Peptic Ulcer	DMF
Gastroenterology	DEXRABEPRAZOLE SODIUM	Peptic Ulcer	DMF
CNS	DONEPEZIL HYDROCHLORIDE	Alzheimer	DMF
Cardiovascular	DOXAZOSIN MESYLATE	Hypertension	DMF
Cardiovascular	DRONEDARONE HYDROCHLORIDE	Arrhythmia	DMF
CNS	DULOXETINE HYDROCHLORIDE	Depression	CEP/DMF
CNS	ELETRIPTAN HYDROBROMIDE	Migraine	DMF
Cardiovascular	ENALAPRIL MALEATE	Hypertension	DMF
Gastroenterology	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	Peptic Ulcer	CEP/DMF

## NOSCH LABORATORIES (NL) India

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Gastroenterology	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	Peptic Ulcer	CEP/DMF
Gastroenterology	ESOMEPRAZOLE SODIUM	Peptic Ulcer	DMF
Endocrinology	GLIMEPIRIDE	Antidiabetic	DMF
Other Therapies	IMATINIB MESYLATE	Neoplasia	DMF
Anti-Infectives	ITRACONAZOLE	Fungal Infection	CEP/DMF
Analgesics & Anti-Inflammatories	KETOROLAC TROMETHAMINE	Acute Pain	DMF
Gastroenterology	LANSOPRAZOLE	Peptic Ulcer	CEP/DMF
Anti-Infectives	LINEZOLID	Bacterial Infection	DMF
Anti-Infectives	LULICONAZOLE	Antifungal	DMF
Gastroenterology	MEBEVERINE HYDROCHLORIDE	Antispasmodic	DMF
CNS	MEMANTINE HYDROCHLORIDE	Alzheimer	DMF
Anti-Infectives	MOXIFLOXACIN BASE	Bacterial Infection	DMF
Anti-Infectives	MOXIFLOXACIN HYDROCHLORIDE ANHYDROUS	Bacterial Infection	CEP/DMF
Anti-Infectives	MOXIFLOXACIN HYDROCHLORIDE MONOHYDRATE	Bacterial Infection	DMF
CNS	NARATRIPTAN HYDROCHLORIDE	Migraine	DMF
CNS	OLANZAPINE	Schizophrenia	CEP/DMF
Gastroenterology	OMEPRAZOLE	Peptic Ulcer	CEP/DMF
Gastroenterology	OMEPRAZOLE MAGNESIUM	Peptic Ulcer	DMF
Gastroenterology	OMEPRAZOLE SODIUM	Peptic Ulcer	DMF
Gastroenterology	PANTOPRAZOLE MAGNESIUM DIHYDRATE	Peptic Ulcer	DMF
Gastroenterology	PANTOPRAZOLE SODIUM SESQUIHYDRATE	Peptic Ulcer	CEP/DMF
Analgesics & Anti-Inflammatories	PHENYRAMIDOL HYDROCHLORIDE	Analgesic	DMF
Cardiovascular	PITAVASTATIN CALCIUM	Antilipemic	DMF
CNS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	Parkinson	DMF
CNS	PREGABALIN	Epilepsy	DMF
CNS	QUETIAPINE FUMARATE	Schizophrenia	CEP/DMF
Gastroenterology	RABEPRAZOLE SODIUM	Peptic Ulcer	CEP/DMF
CNS	RASAGILINE MESYLATE	Parkinson	DMF
Cardiovascular	RIVAROXABAN	Deep Vein Thrombosis	DMF
CNS	RIZATRIPTAN BENZOATE	Migraine	DMF



**NOSCH LABORATORIES (NL)** India

THERAPEUTIC AREA	PRODUCT	INDICATION	CEP/DMF
Cardiovascular	ROSUVASTATIN CALCIUM	Hypercholesterolaemia	CEP/DMF
CNS	SERTRALINE HYDROCHLORIDE	Depression	DMF
Endocrinology	SIBUTRAMINE HYDROCHLORIDE	Obesity	DMF
Other Hormone Disorders	SILODOSIN	Hypertrophy	DMF
CNS	SUMATRIPTAN SUCCINATE	Migraine	DMF
Other Hormone Disorders	TAMSULOSIN HYDROCHLORIDE	Benign Prostatic Hyperplasia	DMF
Anti-Infectives	TERCONAZOLE	Fungal Infection	DMF
CNS	ZOLMITRIPTAN	Migraine	DMF

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## QUÍMICA SINTÉTICA Spain

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Other Therapies	APREMILAST	Psoriasis	√	√	√	√
Endocrinology	BEMPEDOIC ACID	Hypercholesterolaemia	√	4Q21	1Q22	3Q22
CNS	BREXPIRAZOLE	Schizophrenia	√	√	√	√
Cardiovascular	DABIGATRAN	Anti Clot	√	√	√	√
Oncology	DAROLUTAMIDE	Prostate Cancer	√	√	1Q22	3Q22
CNS & Cardiovascular	DROXIDOPA	Hypotension & Parkinson	√	√	√	√
CNS	EDARAVONE	ALS & heart failure	√	√	√	√
Anti-Infectives	EFINACONAZOLE	Antifungal	√	√	√	√
Cardiovascular	ELTROMBOPAG	Aplastic anemia and anti-bleeding	√	√	√	√
Gastroenterology	ELUXADOLINE	Irritable bowel syndrome	√	√	TBD	TBD
Respiratory	IVACAFTOR	Cystic fibrosis	√	√	1Q22	3Q22
Anti-Parasitics	IVERMECTIN	Broad-spectrum antiparasitic agent	√	√	√	√
Other Therapies	LESINURAD	Gout	√	√	TBD	TBD
Respiratory	LUMACAFTOR	Cystic fibrosis	1Q22	1Q22	TBD	TBD
CNS	PALIPERIDONE PALMITATE	Schizophrenia	√	√	√	√
Anti-Infectives	POSACONAZOLE	Fungal Infection	√	√	√	√
Cardiovascular	RIVAROXABAN	Deep Vein Thrombosis	√	√	√	√
Cardiovascular	SELEXIPAG	Pulmonary arterial hypertension	√	√	√	1Q22
Anti-Infectives	SOFOSBUVIR	Hepatitis C	√	√	TBD	TBD
Cardiovascular	TAFAMIDIS	Transthyretin Amyloidosis	√	√	4Q21	2Q22
Cardiovascular	TAFAMIDIS MEGLUMINE	Transthyretin Amyloidosis	√	√	4Q21	2Q22
Respiratory	TEZACAFTOR	Cystic fibrosis	1Q22	2Q22	TBD	TBD

## INDUSTRIALE CHIMICA Italy

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
CNS	BREXANOLONE	Post partum dep.	√	√	TBD	TBD
Other Hormone Disorders	CLASCOTERONE	Acne	√	√	TBD	TBD

## INDUSTRIALE CHIMICA Italy

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Oncology	DUTASTERIDE	BPH	√	√	√	TBD
Hormonal	ELAGOLIX	Uterine fibrosis	√	√	TBD	TBD
Endocrinology	ESTETROL	Contraception	√	√	4Q21	2Q22
Respiratory	FLUTICASONE FUROATE	Asthma	√	√	√	√
CNS	GANAXOLONE	Epilepsy	√	√	TBD	TBD
Respiratory	GLYCOPYRROLATE	Antispasmodic & Antisialagogue	√	√	TBD	TBD
Respiratory	INDACATEROL	COPD	√	√	√	√
Ophthalmologicals	LATANOPROSTENE BUNOD	Glaucoma	√	√	TBD	TBD
Other Therapies	OBETICHOLIC ACID	Primary Biliary Cirrhosis	√	√	√	√
Respiratory	OLODATEROL	COPD	√	√	TBD	TBD
CNS	RAMELTEON	Insomnia	√	√	TBD	TBD
Respiratory	ROFLUMILAST	COPD	√	√	TBD	TBD
Analgesics & Anti-Inflammatories	TAPENTADOL	Acute pain	√	√	TBD	TBD
Other Hormone Disorders	ULIPRISTAL	Emergency Contraception	√	√	√	√
Respiratory	UMECLIDINIUM BROMIDE	COPD	√	√	√	√
Respiratory	VILANTEROL	COPD	√	√	√	√

## CHEMO BIOSYNTHESIS Italy

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Other Hormone Disorders	ABIRATERONE ACETATE	Prostate Cancer	√	√	√	√
Veterinarian	ALTRENOGEST	Contraceptive	√	√	√	√
Anthelmintic	AVERMECTIN	Parasitic infections	√	√	√	4Q21
Oncology	ENZALUTAMIDE	Prostate Cancer	√	√	4Q21	1Q22
Anthelmintic	IVERMECTIN	Parasitic infections	√	√	√	√
CNS	MEMANTINE HYDROCHLORIDE	Alzheimer	√	√	√	√
Hormonal - Contraceptive	NOMEGESTROL	Contraception	√	√	√	√

## CHEMO BIOSYNTHESIS Italy

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Endocrinology	PROGESTERONE	Menopausal hormone therapy	√	√	√	√
Antibiotics	RIFAMICINE	HIV-related tuberculosis	√	√	4Q21	TBD
Antibiotics	RIFAXIME	Travelers diarrhea	√	√	√	2Q22
Cardiovascular	TAFAMIDIS	Transthyretin Amyloidosis	√	√	4Q21	1Q22
Cardiovascular	TAFAMIDIS MEGLUMINE	Transthyretin Amyloidosis	√	√	4Q21	1Q22
Antibiotics	VALNEMULINE HYDROCHLORIDE	Gastrointestinal infections	√	√	√	√

## MAPRIMED Argentina

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Cardiovascular	AMLODIPINE BESYLATE	Anti-angine; Antihypertensive	√	√	√	TBD
Other Therapies	APREMILAST	Psoriasis	√	√	√	√
Gastroenterology	DEXLANSOPRAZOLE	Peptic Ulcer	√	√	√	TBD
Oncology	ENZALUTAMIDE	Prostate Cancer	√	√	√	√
Cancer	IBRUTINIB	Mantle cell lymphoma (MCL)	√	√	√	TBD
Endocrinology	IPRAGLIFOZIN L-PROLINE	Treatment of Type 2 Diabetes	√	√	√	TBD
CNS	OZANIMOD	Multiple sclerosis	√	√	√	1Q22
Cardiovascular	RIVAROXABAN	Deep Vein Thrombosis	√	√	√	√
Endocrinology	VILDAGLIPITIN	Treatment of Type 2 Diabetes	√	√	√	TBD

## UNIVERSAL PHARMA Spain

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
CNS	ARIPIRAZOLE (Sterile)	Schizophrenia	√	√	√	3Q22
Respiratory & Digestive	BUDESONIDE (Sterile)	Asthma & Crohn disease	√	√	√	2Q22

## UNIVERSAL PHARMA Spain

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Ophthalmologicals	LOTEPREDNOL (Sterile)	Eye swelling	√	√	√	2Q22
CNS	PALIPERIDONE PALMITATE (Sterile)	Schizophrenia	√	√	√	3Q22
Ophthalmologicals	BRINZOLAMIDE (Sterile)	Glaucoma	√	√	√	2Q22

## TYCHE India

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Respiratory	NINTEDANIB	Idiopathic pulmonary fibrosis	√	√	√	4Q22
Respiratory	PIRFENIDONE	Pulmonary fibrosis	√	√	√	√

## SMS India

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Endocrinology	CANAGLIFLOZIN	Diabetes	√	4Q21	1Q22	4Q22
Endocrinology	DAPAGLIFLOZIN	Diabetes	√	√	√	√
Endocrinology	EMPAGLIFLOZIN	Diabetes	√	√	√	√
Endocrinology	LINAGLIPTIN	Diabetes	√	1Q22	TBD	TBD
Urology	MIRABEGRON	Incontinence	√	√	√	√
CNS	PERAMPANEL	Epilepsy	√	√	√	√
Cardiovascular	RANOLAZINE	Heart Failure	√	√	√	√
Endocrinology	SITAGLIPTIN HCL	Diabetes	√	√	√	√
Endocrinology	SITAGLIPTIN PHOSPHATE	Diabetes	√	√	√	√
Endocrinology	VILDAGLIPTIN	Diabetes	√	√	√	√

## APIS INITIAL DEVELOPMENTS

THERAPEUTIC AREA	PRODUCT	INDICATION
Oncology	2-METHOXYESTRADIOL	Asthma
Respiratory	CICLESONIDE	Asthma
Endocrinology	ERTUGLIFLOZIN	Type-2 Diabetes
Cardiovascular	FINERENONE	Kidney disease
Anti-infectives	IBREXAFUNGERP	Vulvovaginal candidiasis
Oncology	RELUGOLIX	Prostate cancer
Respiratory	REVEFENACIN	COPD
CNS	RIMEGEPANT	Migraine treatment
Dermatology	TIRBANIBULIN	Actinic keratosis
Cardiovascular	VERICIGUAT	Heart failure
Urology	VIREGRON	Overactive bladder
Immunosuppressant	VOCLOSPORIN	Lupus nephritis

\* pending on the prioritization of the project

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