

لجنة تسجيل شركات ومصانع المستحضرات الصيدلانية ومنتجاتها

الربع الأول ٢٠٢٤

تسجيل المستحضرات



قرارات لجنة تسجيل شركات ومصانع المستحضرات الصيدلانية ومنتجاتها

قررت لجنة تسجيل شركات ومصانع المستحضرات الصيدلانية تسجيل المستحضرات حسب التالي:

يناير ٢٠٢٤

الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Vertex Pharmaceuticals (Europe) Limited - United Kingdom	Exagamglogene Autotemcel 4-13*10 ⁶ cells/ml	Casgevly
Eisai Inc – USA	Lemborexant 5mg	Dayvigo
Eisai Inc – USA	Lemborexant 10mg	Dayvigo
AbbVie Ltd. - United Kingdom	Atogepant 10 mg	AQUIPTA
AbbVie Ltd. - United Kingdom	Atogepant 60 mg	AQUIPTA
Jazeera Pharmaceutical Industries – Saudi Arabia	Cefixime Trihydrate 40 mg/ml	Suprax
Sudair Pharma Company- Saudi Arabia	Treprostinil monohydrate 2.5 mg/mL	Redunix
Sudair Pharma Company - Saudi Arabia	Treprostinil monohydrate 5 mg/mL	Redunix
Jerash Pharmaceutical limited company - Jordan	Ambroxol hydrochloride 0.6%	Ambrolyt
EVER Valinject GmbH - Austria	Cabazitaxel 10 mg/ml	Anavalin
Eva Pharma for Pharmaceuticals and Medical Appliances - Egypt	Bicalutamide 50 mg	Bicapros
Pharmaceutical Solutions Industry Ltd - Saudi Arabia	Salbutamol Sulphate 5 mg/ml	Bronchovent
Tabuk Pharmaceuticals Manufacturing Company – Saudi Arabia	Tigecycline 50 mg	Cabitac
NEAPOLIS PHARMA-Tunisia	Dasatinib Monohudrate 140 mg	Dasatinib Neapolis
Amman Pharmaceutical Industries - Jordan	Xylometazoline Hydrochloride 0.05%	Decozal
Jerash Pharmaceutical limited company - Jordan	Ketoprofen 2.5%	Deeprub Gel 2.5%
Boston Oncology Arabia - Saudi Arabia	Everolimus 5 mg	Everolimus BOS
Boston Oncology Arabia - Saudi Arabia	Everolimus 10 mg	Everolimus BOS



الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Saudi Pharmaceutical Industries - Saudi Arabia	Lidocaine 100 mg/ml	Lipro SPRAY
Spectro Pharma – Saudi Arabia	Pemetrexed 500 mg	Penmat
Advanced Pharmaceutical Industries Ltd. - Saudi Arabia	Tigecycline 50 mg	Vantag
Med City Pharma – Saudi Arabia	Voriconazole 200 mg	Voriconazole MCP
Sudair Pharma Company – Saudi Arabia	Fluticasone Propionate 125 mcg	Flohale
Sudair Pharma Company – Saudi Arabia	Fluticasone Propionate 250 mcg	Flohale
Janssen Cilag International NV - Belgium	Selexipag 400 µg	Uptravi
Janssen Cilag International NV - Belgium	Selexipag 800 µg	Uptravi
Saudi AmaroX Industrial Company – Saudi Arabia	Sapropterin dihydrochloride 500 mg	Sapropterin AmaroX
Saudi AmaroX Industrial Company – Saudi Arabia	Sapropterin dihydrochloride 100 mg	Sapropterin AmaroX
NEAPOLIS PHARMA - Tunisia	Azacitidine 100 mg	Azacitidine Neapolis
Jamjoom Pharmaceuticals Company – Saudi Arabia	Brimonidine Tartrate 1.5 mg/ml (0.15%)	Brimo-P
Med City Pharma - Saudi Arabia	Dapoxetine Hydrochloride 30 mg	Endura
Med City Pharma - Saudi Arabia	Dapoxetine Hydrochloride 60 mg	Endura
Tabuk Pharmaceuticals Manufacturing Company – Saudi Arabia	Bivalirudin 250 mg	Novalir
Riyadh Pharma -KSA	Olmesartan Medoxomil 40 mg, Hydrochlorothiazide 25 mg	Olmترول Plus
Riyadh Pharma -KSA	Olmesartan Medoxomil 40 mg, Hydrochlorothiazide 12.5 mg	Olmترول Plus

الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Spectro Pharma – Saudi Arabia	Atomoxetine Hydrochloride 40 mg	Acumen
Spectro Pharma – Saudi Arabia	Atomoxetine Hydrochloride 60 mg	Acumen
Eva Pharma for Pharmaceuticals and Medical Appliances - Egypt	Diacerein 50 mg	Diacerein
Alrai Pharmaceutical Industry Co L L C - KSA	Perindopril Arginine 5 mg	Cenoril
Alrai Pharmaceutical Industry Co L L C - KSA	Perindopril Arginine 10 mg	Cenoril
Sudair Pharma Company -KSA	Vancomycin Hydrochloride 5 mg/ml (500 mg)	Ultavan
Sudair Pharma Company - KSA	Vancomycin Hydrochloride 5 mg/ml (1000 mg)	Ultavan
Med City Pharma -KSA	Teriflunomide 14 mg	Myteb
Saudi Pharmaceutical Industries & Medical Appliances Corporation – Saudi Arabia	Linagliptin 5 mg	Lavinda
Sudair Pharma Company – Saudi Arabia	Empagliflozin 25 mg	Empagliflozin SPC
Sudair Pharma Company – Saudi Arabia	Empagliflozin 10 mg	Empagliflozin SPC
Hainan Shuangcheng Pharmaceuticals Co., Ltd. – China	Bivalirudin 250 mg	Bivalirudin for injection
Sanofi Winthrop Industrie - France	Nirsevimab-alip 100 mg	Beyfortus
Sanofi Winthrop Industrie - France	Nirsevimab-alip 50 mg	Beyfortus
Janssen-Cilag International NV - Belgium	Teclistamab 10 mg/ml	Tecvayli
Janssen-Cilag International NV - Belgium	Teclistamab 90 mg/ml	Tecvayli
Med City Pharma - KSA	Valsartan 80 mg	Velseva
Bayer AG - Germany	Aflibercept 114.3 mg/ml	Eylea

الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
National Pharmaceutical Industries Co. (SAOC) - Oman	Ciprofloxacin 500 mg	Omacip
Saudi AmaroX Industrial Company – Saudi Arabia	Linagliptin 5 mg	Liptyn
Med City Pharma – Saudi Arabia	Apixaban 2.5 mg	Apdx
Med City Pharma – Saudi Arabia	Apixaban 5 mg	Apdx
National Pharmaceutical Industries Co.(SAOG) - Oman	Cetirizine Hydrochloride 10 mg	Omcet
ANFARM HELLAS S.A. - Greece	Clarithromycin 500 mg	MAXILIN
Alrai Pharmaceutical Industry Co L L C – Saudi Arabia	Sitagliptin 50 mg	Sita
Alrai Pharmaceutical Industry Co L L C – Saudi Arabia	Sitagliptin 100 mg	Sita
Spectro Pharma - KSA	Paricalcitol 5 µg/ml	Paricalcitol Spectro
Janssen-Cilag International NV - Belgium	Teclistamab 90 mg/ml	Tecvayli
Biosimilars Collaborations Ireland Limited - Ireland	Insulin Glargine 100 U/ml	Semglee
Laboratorios Salvat S.A., Spain	Ciprofloxacin hydrochloride 3 mg/ml + Fluocinolone acetone 0.25 mg/ml	Cetraxal plus
Amoun Pharmaceutical Company -Egypt	VITAMIN K1 (Phytomenadione) 10 mg	Haemokion
Janssen-Cilag International NV - Belgium	Teclistamab 90 mg/ml	Tecvayli
Alpha Pharma - Saudi Arabia	Baclofen 10 mg	Loanta
Batterjee Pharmaceutical factory - Saudi Arabia	Rosuvastatin calcium 20 mg	ROSA
Batterjee Pharmaceutical factory - Saudi Arabia	Rosuvastatin calcium 10 mg	ROSA
Med City Pharma - KSA	Valsartan 160 mg	Velseva

الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Riyadh Pharma -KSA	Olmesartan Medoxomil 20 mg, Hydrochlorothiazide 12.5 mg	Olmetrol Plus
Novitium Pharma LLC -US	Sildenafil 10 mg/ml	Sildenafil for Oral Suspension
Spectro Pharma – Saudi Arabia	Atomoxetine Hydrochloride 10 mg	Acumen
Spectro Pharma – Saudi Arabia	Atomoxetine Hydrochloride 18 mg	Acumen
Spectro Pharma – Saudi Arabia	Atomoxetine Hydrochloride 25 mg	Acumen

الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
MS Pharma Saudi – Saudi Arabia	Ranibizumab 10 mg/ml	Ravegza
Mylan IRE Healthcare Limited – Ireland	Etanercept 50 mg	Nepexto
Baxter Healthcare Corporation, USA	Thrombin alfa 5,000 IU	Recothrom
Baxter Healthcare Corporation, USA	Thrombin alfa 20,000 IU	Recothrom
Horizon Therapeutics DAC -Ireland	Teprotumumab 500 mg	Tepezza
Boston Oncology Arabia-KSA	Tocilizumab 20 mg/ml (80 mg)	Tyenne
Boston Oncology Arabia-KSA	Tocilizumab 20 mg/ml (200 mg)	Tyenne
Boston Oncology Arabia-KSA	Tocilizumab 20 mg/mL (400 mg)	Tyenne
Boston Oncology Arabia- KSA	Tocilizumab 162 mg 4 pre-filled syringe (0.9ml)	Tyenne
Boston Oncology Arabia- KSA	Tocilizumab 162 mg 1 pre-filled pen (0.9ml)	Tyenne
Amgen Europe BV - Netherlands	Adalimumab 20 mg	Amgevita
Insmmed Netherlands B.V. – Netherlands	Amikacin sulfate liposomal formulation - 590 mg	Arikayce
Gen.Orph - France	Miglustat 100 mg	Miglustat Gen Orph
Amman Pharmaceutical Industries - Jordan	Xylometazoline HCl 0.1%	Decozal menthol
Pharma Pharmaceutical Industry - Saudi Arabia	Cinacalcet hydrochloride 30 mg	Glandacet
Pharma Pharmaceutical Industry - Saudi Arabia	Cinacalcet hydrochloride 60 mg	Glandacet



الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Pharma Pharmaceutical Industry - Saudi Arabia	Cinacalcet hydrochloride 90 mg	Glandacet
Amman Pharmaceutical Industries-Jordan	Olopatadine HCl 0.1%	iPAT
Gulf Pharmaceutical industries (Julphar) - UAE	Aspirin (Acetylsalicylic Acid) 81 mg	Jusprin
MS Pharma Saudi -KSA	Lenalidomide 5 mg	Lammalid
MS Pharma Saudi -KSA	Lenalidomide 10 mg	Lammalid
MS Pharma Saudi -KSA	Lenalidomid 15 mg	Lammalid
MS Pharma Saudi -KSA	Lenalidomide 25 mg	Lammalid
Glaxo Saudi Arabia Ltd. – Saudi Arabia	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted) 120 micrograms	Arexvy
CSL International PTY LTD – Germany	Factor XIII 250 IU/4 ml	Fibrogammin
CSL Behring GmbH - Germany	Factor XIII 1250 IU/20 ml	Fibrogammin
Sanofi Aventis France - France	Oxomemazine 0.33 mg/ml	Mucoplexil
AJA Pharmaceutical Industries Company Ltd - Saudi Arabia	Rivaroxaban 20 mg	Roxban
AJA Pharmaceutical Industries Company Ltd - Saudi Arabia	Rivaroxaban 15 mg	Roxban
AJA Pharmaceutical Industries Company Ltd - Saudi Arabia	Rivaroxaban 15 mg	Roxban
AJA Pharmaceutical Industries Company Ltd - Saudi Arabia	Rivaroxaban 10 mg	Roxban
Doctors Pharmaceutical manufacturer – Saudi Arabia	Rosuvastatin Calcium 40 mg	Docrosa
Doctors Pharmaceutical manufacturer – Saudi Arabia	Rosuvastatin Calcium 20 mg	Docrosa



الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Doctors Pharmaceutical manufacturer – Saudi Arabia	Rosuvastatin Calcium 10 mg	Docrosa
Doctors Pharmaceutical manufacturer – Saudi Arabia	Rosuvastatin Calcium 5 mg	Docrosa
Med City Pharma – Saudi Arabia	Valsartan 80 mg, Hydrochlorothiazide 12.5 mg	Avyska HCT
Med City Pharma – Saudi Arabia	Valsartan 160 mg, Hydrochlorothiazide 25 mg	Avyska HCT
AS Kalceks - Latvia	Noradrenaline tartrate 1 mg/ml	Norepinephrine Kalceks
Med City Pharma – Saudi Arabia	Valsartan 160 mg, Hydrochlorothiazide 12.5 mg	Avyska HCT
Sudair Pharma Company – Saudi Arabia	Abiraterone acetate 500 mg	Abiraterone SPC
Saudi AmaroX Industrial Company – Saudi Arabia	Daptomycin 350 mg	Daptomycin Amarox
Saudi AmaroX Industrial Company – Saudi Arabia	Daptomycin 500 mg	Daptomycin Amarox
Saudi AmaroX Industrial Company – Saudi Arabia	Tolterodine tartrate 2 mg	Uridisitol
Spectro Pharma - Saudi Arabia	Topiramate 100 mg	Eptop
Spectro Pharma - Saudi Arabia	Topiramate 50 mg	Eptop
Spectro Pharma - Saudi Arabia	Topiramate 25 mg	Eptop
Pfizer Europe – Belgium	RSV subgroup A stabilised prefusion F antigen1,2 60 micrograms	ABRYSVO (10 Vials)
Pfizer Europe – Belgium	RSV subgroup A stabilised prefusion F antigen1,2 60 micrograms	ABRYSVO (1 Vial)
Pharmacosmos, Denmark	Ferric Derisomaltose 100 mg/ml	Monofer
Saudi AmaroX Industrial Company – Saudi Arabia	Polyethylene Glycol 3350	Eulax
Aspen Healthcare Malta Limited - Malta	Ulipristal acetate 30 mg	Ecinq

الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Pfizer Europe MA EEIG, Belgium	Pegfilgrastim 6 mg/ 0.6 mL	Nyvepria
IBSA Institut Biochimique SA - Switzerland	Sildenafil 25 mg	Ultasil
IBSA Institut Biochimique SA - Switzerland	Sildenafil 50 mg	Ultasil
IBSA Institut Biochimique SA - Switzerland	Sildenafil 100 mg	Ultasil
Boston Oncology Arabia	Fomepizole 1 g/mL	Fomepizole BOS
Eva Pharma for Pharmaceuticals and Medical Appliances - Egypt	Gefitinib 250 mg	Lunginib
MS Pharma Saudi – Saudi Arabia	Tiotropium bromide 13 µg	Triova
MS Pharma - Saudi Arabia	Atracurium Besylate 10 mg /ml	Retalex
Tabuk Pharmaceutical Manufacturing Company – Saudi Arabia	Linagliptin 5 mg	Linajent
Saudi AmaroX Industrial Company - Saudi Arabia	Macitentan 10 mg	Opsutin
Saudi AmaroX Industrial Company - Saudi Arabia	Famotidine 10 mg	Peploc
Advanced Pharmaceutical Industries Ltd. Saudi Arabia	Travoprost 0.04 mg/ml	Ravopro
Saudi AmaroX Industrial Company – Saudi Arabia	Olmesartan Medoxomil 20 mg	Olmy
Saudi AmaroX Industrial Company – Saudi Arabia	Olmesartan Medoxomil 40 mg	Olmy
Saudi AmaroX Industrial Company – Saudi Arabia	Sapropterin dihydrochloride 100 mg	Sapropterin AmaroX
Saudi AmaroX Industrial Company – Saudi Arabia	Sugammadex Sodium 100 mg/ml	Sudex
Eva Pharma for pharmaceuticals and medical appliances (Eva Pharma) - Egypt	Tiotropium bromide monohydrate 18 mcg	Tiotropium Eva

الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Saudi AmaroX Industrial Company - Saudi Arabia	Famotidine 20 mg	Peploc
Saudi AmaroX Industrial Company - Saudi Arabia	Famotidine 40 mg	Peploc
Boston Oncology Arabia – Saudi Arabia	Etanercept 25 mg	Nepexto
Boston Oncology Arabia – Saudi Arabia	Etanercept 50 mg	Nepexto
Incyte Biosciences International Sarl - Switzerland	Tafasitamab 200 mg	Minjuvi
AstraZeneca UK Ltd - UK	Acalabrutinib maleate 100 mg	Calquence
Boston Oncology Arabia - Saudi Arabia	Bimatoprost 0.1 mg /ml	Bimatoprost BOS
Batterjee Pharmaceutical Factory - Saudi Arabia	Celecoxib 200 mg	Cebatix
Middle East Pharmaceutical Industries Co. Ltd. (Avalon Pharma) – Saudi Arabia	Solifenacin Succinate 10 mg	Uroleph
Middle East Pharmaceutical Industries Co. Ltd. (Avalon Pharma) – Saudi Arabia	Solifenacin Succinate 5 mg	Uroleph
Pharma Pharmaceutical Industry - Saudi Arabia	Abiraterone Acetate 500 mg	Abroten
Pharma Pharmaceutical Industry - Saudi Arabia	Abiraterone Acetate 250 mg	Abroten
Boston Oncology Arabia – Saudi Arabia	Busulfan 6 mg /ml	Busulfan BOS
Jazeera Pharmaceutical Industries – Saudi Arabia	Tirofiban hydrochloride monohydrate 250 mcg/ml	Fibrosta
Tillomed Laboratories Limited - UK	Trientine dihydrochloride 250 mg	Trientine dihydrochloride Tillomed
Bristol-Myers Squibb Company – USA	Deucravacitinib 6 mg	Sotyktu
Saudi AmaroX Industrial Company, Saudi Arabia	Rufinamide 40 mg/ml	Rufzel
Saudi AmaroX Industrial Company – Saudi Arabia	Sugammadex Sodium 100 mg/ml	Sudex



الشركة المسوقة	الاسم العلمي مع التركيز	الاسم التجاري
Alrai Pharmaceutical Industry Co. (L.L.C) - Saudi Arabia	Aripiprazole 10 mg	Arify
Alrai Pharmaceutical Industry Co. (L.L.C) - Saudi Arabia	Aripiprazole 15 mg	Arify
Saudi AmaroX Industrial Company – Saudi Arabia	Atazanavir Sulfate 150 mg	Ataben
Saudi AmaroX Industrial Company – Saudi Arabia	Atazanavir Sulfate 200 mg	Ataben



تسجيل المصانع

قرارات لجنة تسجيل شركات ومصانع المستحضرات الصيدلانية ومنتجاتها

قررت لجنة تسجيل شركات ومصانع المستحضرات الصيدلانية تسجيل المصانع حسب التالي:

يناير ٢٠٢٤

الدولة	اسم المصنع
السعودية	Jamjoom Pharmaceuticals Factory Company
أمريكا	Charles River Laboratories Inc.
بريطانيا	Biocube 2 (Roselin Cell Therapeis, Ltd)
أمريكا	AGC Biologics Inc.
أمريكا	Granules Pharmaceuticals Inc.
اسبانيا	Bieffe Medital S.A.
السعودية	Apex Pharma
مالطا	Pharmacare Premium Ltd
جنوب افريقيا	ASPEN SA OPERATIONS (PTY) LTD (Unit 4)
أمريكا	Xcelience, LLC
فرنسا	Laboratoires Galeniques Vernin
فرنسا	Laboratoires MAYOLY SPINDLER

الدولة	اسم المصنع
سنغافورا	Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd.
ايرلندا	Regeneron Ireland Designated Activity Company
إيطاليا	Fulton Medicali S.p.A.
أمريكا	Almac Clinical Services LLC
الصين	AmbioPharm, Inc.
الهند	Concord Biotech Limited

الدولة	اسم المصنع
الهند	Gland Pharma Limited
ألمانيا	EVER Pharma Jena GmbH
الهند	Credo Life Sciences Private Limited
الصين	Hainan Poly Pharm. Co.K Ltd
سنغافورا	GlaxoSmithKline Biologicals
أمريكا	Tris Pharma
مصر	EVA PHARMA for Pharmaceutical Industries.
السعودية	MIDDLE EAST PHARMACEUTICAL INDUSTRIES (AVALON PHARMA)
بريطانيا	SYRI LIMITED
الهند	SERUM INSTITUTE OF INDIA PVT. LTD., (SIIPL)
الهند	M/s. Steril-Gene Life Sciences (P) Ltd.
أمريكا	UPM Pharmaceuticals

شكراً

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

