

Rejection for registration (2025)

N	Date	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply
1	10.01.2025	Dopamine-Theo	dopamine (dopamine hydrochloride)	solution for infusion	200mg/5ml; (10) ampoules 5ml	Laboratorio Medinfar-Produtos Farmaceuticos, S.A., Rua Henrique Paiva Couceiro, n.0 27 Venda Nova, Amadora, 2700-451- batch releaser, Laboratorios Vitoria, S.A., Rua Elias Garcia, n.0 28, Amadora, 2700-327, Portugal- bulk manufacturer, packager, quality control	Portugal	Laboratorio Medinfar-Produtos Farmaceuticos, S.A. Rua Henrique Paiva Couceiro, n.0 29 Venda Nova, 2700-451 Amadora	Portugal	PoM
2	12.03.2025	Eezpain	oil of gaultheria, eucaliptus oil, turpentine oil, clove oil, menthol, camphor	gel	0,845ml+0,555ml+0,288ml+0,12ml+0,375g+0,125g; plastic tube 25g	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Pakistan	OTC
3	04.04.2025	Progesterone Depo	hydroxyprogesterone caproate (17-hydroxyprogesterone caproate)	solution for injection	250mg/ml; (5/1x5) ampoules 1ml, in a plastic tray	Galenika a.d., Beograd, Batajnicki drum b.b., 11080 Belgrade- secondary packager, quality control, batch releaser, Panpharma GmbH, Bunsenstrasse 4, 22946 Trittau, Germany- bulk manufacturer, primary packager	Serbia	Galenika a.d., Beograd, Batajnicki drum b.b., 11080 Belgrade	Serbia	PoM
4	04.04.2025	Moxonidin Avexima	moxonidine	tablets film-coated	0,2mg; (60/6x10), (60/3x20), (100/5x20), in blister	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM
5	04.04.2025	Moxonidin Avexima	moxonidine	tablets film-coated	0,4mg; (60/6x10), (60/3x20), (100/5x20), in blister	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284, Russia	Russia	PoM

6	04.04.2025	Novex Montelukast	montelukast (montelukast sodium)	tablets chewable	5mg; (14/1x14), in blister	Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad	Pakistan	Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad	Pakistan	PoM
7	04.04.2025	Novex Montelukast	montelukast (montelukast sodium)	tablets film-coated	10mg; (14/1x14), in blister	Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad	Pakistan	Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad	Pakistan	PoM
8	06.05.2025	Indotrex	cetorelix (cetorelix acetate)	solution for s/c injection	0,25mg/0,5ml; pre-filled syringe 0,5ml	Gufic Biosciences Limited, Survey No. 171, N. H. No. 8, Near Grid, Kabilpore Navsari - 396424, Gujarat-bulk manufacturer, packager, quality control, batch releaser	India	Gufic Biosciences Ltd., National Highway No. 8, Near Grid, Kabilpore-396424, Navsari, Gujarat	India	PoM
9	06.05.2025	Montol	montelukast (montelukast sodium)	tablets film-coated	10mg; (28/2x14) in blister	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081, Lefkosia- secondary packaging, batch releaser, Saneca Pharmaceuticals a.s., Nitrianska 100, 92027 Hlohovec, Slovakia- bulk manufacturer, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- primary packaging	Cyprus	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081, Lefkosia, Cyprus	Cyprus	PoM
10	08.05.2025	Silodosin Ibn Al Haytham	silodosin	capsules	8mg; (20/2x10) in blister	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	PoM
11	08.05.2025	Silodosin Ibn Al Haytham	silodosin	capsules	4mg; (20/2x10) in blister	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	PoM
12	23.05.2025	Demiflu Max Cold	paracetamol, guaifenesin, phenylehrine (phenylephrine hydrochloride)	powder for oral solution	1000mg+200mg+12,2mg; (8) sachets	FORTEX NUTRACEUTICALS LTD. 10, Prohladen kat street, Suhodol district, 1362 Sofia	Bulgaria	DEMI PHARM LLC, Griboyedovi 12, ap. 25, Sevan 1501	Republic of Armenia	OTC
13	18.06.2025	Artheek SP	articaine (articaine hydrochloride), epinephrine (adrenaline)	solution for injection	40mg/ml+10mcg/ml; (50) cartridges 1,8ml	New Stetic S.A. Carrera 53, No 50-09, GUARNE, ANTIOQUIA	Colombia	New Stetic S.A. Carrera 53, No 50-09, GUARNE, ANTIOQUIA	Colombia	PoM

14	25.08.2025	Asthalin	salbutamol (salbutamol sulfate)	aerosol for inhalation dosed	100mcg/dose; aluminium container 19ml with metering valve and inhaler	Cipla Ltd., Plot No. L-139 to L-146, Verna Industrial Estate, Verna, Salcete Goa, 403722	India	Cipla Ltd., Cipla House, Peninsula Business Park, Ganapatrao Kadam Marg, Lower Parel, Maharashtra, 400 013, Mumbai	India	PoM
15	25.08.2025	Speman forte N	withania somnifera, asteracantha longifolia, lactuca serriola, mucuna pruriens, mosaic gold, argyrea speciosa, tribulus terrestris, leptadenia reticulata, rauwolfia serpentina, parmelia perlata	tablets	39mg+19mg+10mg+10mg+10mg+1 9mg+19mg+19mg+18,75mg+10mg; (100) in plastic container	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	PoM
16	25.08.2025	Speman N	withania somnifera, asteracantha longifolia, lactuca serriola, mucuna pruriens, mosaic gold, argyrea speciosa, tribulus terrestris, leptadenia reticulata, parmelia perlata	tablets	65mg+32mg+16mg+16mg+16mg+ 32mg+32mg+32mg+16mg; (100) in plastic container	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	Himalaya Wellness Company, Makali, Bengaluru, 562 163	India	PoM
17	02.10.2025	FEMION	tribulus terrestris, withania somnifera, zingiber officinalis, mucuna pruriens, asparagus racemosus, saraca indica, valeriana hardwickii, foeniculum vulgare, coriandrum sativum, vitex agnus castus	capsules	100mg+100mg+50mg+25mg+25mg +25mg+25mg+17mg+17mg+16mg; (20) plastic vial, (60) plastic vial	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	OTC
18	02.10.2025	Riidor	cefepime (cefepime hydrochloride)	powder for solution for injection or infusion	1000mg; (1) glass vial and (50) glass vials 15ml	AbiPharm LLC, Mtskheta district, village Tsilkani, 3319- bulk manufacturer, packager, batch releaser, Globaltest LTD, St. Tbilisi, Chachava 1 / Ljubljana 5, Georgia- quality control(physicochemical), PharmaTech CJSC, Raffi 111 str., 0064, Yerevan, Republic of Armenia- quality control(microbiological)	Georgia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM

19	02.10.2025	AMOXICILLIN 250mg/5ml	amoxicillin (amoxicillin trihydrate)	powder for oral suspension	250mg/5ml; powder in 100ml plastic bottle and measuring cup	Medicamen Biotech Ltd., SP-1192 A&B, Phase-IV, Industrial Area, Bhiwadi 301019, Dist. Alwar, Rajasthan	India	Troge Scientific Research India PVT.LTD., Tower C, Unit No- A-12-A, 2nd floor, Alpathum, Sector-90, Noida 201305, Uttar Pradesh	India	PoM
20	02.10.2025	Priorix	live attenuated measles virus(Schwarz strain), live attenuated mumps virus(RIT 4385 strain), live attenuated rubella virus(Wistar RA 27/3 strain)	powder and solvent for solution for injection	not less than 103.0CCID50/dose+not less than 103.7CCID50/dose+not less than 103.0CCID50/dose; (100(200 dose)) glass vial, (100) solvent in ampoule 1ml	GlaxoSmithkline Biologicals SA, Belgium, Parc de la Noire Epine, Avenue Fleming 20, Wavre, 1300-secondary packager, batch releaser, Fidia Farmaceutici S.P.A., Via Ponte Della Fabbrica 3/A-35031 Albano Terme (PD), Italy-bulk manufacturer, primary packager, Delpharm Tours Rue Paul Langevin BP 90241, 37172 Chambray-les-Tours, France-solvent manufacturer	Belgium	GlaxoSmithKline Biologicals s.a., Rue de l'Institut, 89 B-1330 Rixensart	Belgium	PoM
21	03.10.2025	Ibulex	ibuprofen	gel for external use	50mg/g; aluminium tube 30g, 50g, 60g, 100g aluminum container BOV 50g	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Danhson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	OTC
22	16.10.2025	Ceftriaxone GIGA pharm	ceftriaxone (ceftriaxone sodium)	powder for solution for injection/ infusion	1000mg; glass vial 10ml	Health Care Formulations Pvt. Ltd., C/8, Sardar Estate, Ajwa Road, Vadodara	India	Giga Farm LLC, Gogunts st. 3/5, Gyumri	Republic of Armenia	PoM
23	16.10.2025	AnviMax	paracetamol, ascorbic acid, calcium gluconate (calcium gluconate monohydrate), rimantadine (rimantadine hydrochloride), rutoside (rutin), loratadine	powder for oral solution with raspberry flavour	360mg+300mg+100mg+50mg+20 mg+3mg; (6) sachets, (12) sachets, (24) sachets	JSC Rafarma, 399540, Lipetsk Region, Terbunsky district, Terbuny village, Dorozhnaya St., Building 6A	Russia	SotexPharmFirm CJSC, bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	OTC
24	16.10.2025	AnviMax	paracetamol, ascorbic acid, calcium gluconate (calcium gluconate monohydrate), rimantadine (rimantadine hydrochloride), rutoside (rutin), loratadine	powder for oral solution with lemon flavour	360mg+300mg+100mg+50mg+20 mg+3mg; (6) sachets, (12) sachets, (24) sachets	JSC Rafarma, 399540, Lipetsk Region, Terbunsky district, Terbuny village, Dorozhnaya St., Building 6A	Russia	SotexPharmFirm CJSC, bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	OTC

25	11.11.2025	Nebidon 5	nebivolol (nebivolol hydrochloride)	tablets	5mg; (100/10x10) in blister	CADILA PHARMACEUTICALS LTD. PLOT NO. 1389 TRASAD ROAD, DHOLKA- 382225, Dist: AHMEDABAD, GUJARAT STATE	India	CADILA PHARMACEUTICALS LTD. PLOT NO. 1389 TRASAD ROAD, DHOLKA- 382225, Dist: AHMEDABAD, GUJARAT STATE	India	PoM
26	14.11.2025	Etorixin	etoricoxib	tablets film-coated	90mg; (10/1x10) in blister	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kvality Pharmaceuticals Limited, Village Nag Kalan, Majitha Road, Majitha, Amritsar, India- bulk manufacturer, packager, quality control	Republic of Armenia	Primus Med LLC, 75/126 Nar Dos str., 0070, Yerevan	Republic of Armenia	PoM
27	14.11.2025	Prednisolone	prednisolone(prednisolone acetate)	suspension ophthalmic	10mg/ml; plastic bottle 5ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kvality Pharmaceuticals Ltd., Village Nag Kalan, Majitha Road, Amritsar, India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM
28	01.12.2025	Tamizet	tamsulosin (tamsulosin hydrochloride)	capsules	0,4mg; (10/1x10) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM
29	01.12.2025	Testosteron Depo	testosterone (testosterone enantate)	solution for injection	250mg/ml; (5) ampoules 1ml	Galenika a.d., Batajnicki drum b.b., 11080 Belgrad-Zemun- secondary packager, quality control (physicochemical), batch releaser, Panpharma GmbH, Bunsenstrasse 4, 22946, Trittau, Schleswig-Holstein, Germany- bulk manufacturer, primary packager, Faculty of Pharmacy, University of Belgrade, Vojvode Stepe 450, Belgrade, 11000, Serbia- quality control (microbiological)	Serbia	Galenika a.d., Batajnicki drum b.b., 11080 Belgrade	Serbia	PoM

30	12.12.2025	LACTON	lactobacillus bacteria sporogenes, folic acid, cyanocobalamin	capsules	not less than 180x10 ⁶ +0,15mg+0,015mg; (20/2x10) in blister	M/S Protech Biopharma Pvt. Ltd., Plot No. 4/48 I & 4/49 I, Zone-I, SIDCO Industrial Growth Centre, Lassipora, Pulwama (J & K)	India	M/S Protech Biopharma Pvt. Ltd., Plot No. 4/48 I & 4/49 I, Zone-I, SIDCO Industrial Growth Centre, Lassipora, Pulwama (J & K)	India	OTC
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