

Rejection for registration (2023)

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	06.03.2023	Doxorubicine Hydrochloride For Injection 10mg	doxorubicin (doxorubicin hydrochloride)	powder lyophilized for solution for injection	10mg; glass vial 5ml	Bruck Pharma Pvt. Ltd, Plot No. 188/1 to 6, 189/1, 190/2 to 4, Athiyawad, Dabhel, Daman-396 210	India	Swiss Parenterals Ltd., Office No.: 62, 6th floor, Titanium, Corporate road, Opp. Auda garden lane, Prahlad nagar, Ahmedabad-380015, Gujarat	India	PoM
2	06.03.2023	Doxorubicine Hydrochloride For Injection USP	doxorubicin (doxorubicin hydrochloride)	powder lyophilized for solution for injection	50mg; glass vial 30ml	Bruck Pharma Pvt. Ltd, Plot No. 188/1 to 6, 189/1, 190/2 to 4, Athiyawad, Dabhel, Daman-396 210	India	Swiss Parenterals Ltd., Office No.: 62, 6th floor, Titanium, Corporate road, Opp. Auda garden lane, Prahlad nagar, Ahmedabad-380015, Gujarat	India	PoM

3	06.03.2023	Morphine hydrochloride	morphine (morphine hydrochloride)	solution for injection	10mg/ml; (100/20x5/) ampoules 1ml in blister	Limited Liability Company "Kharkiv Pharmaceutical Enterprise "Zdorovyie Narodu", 61002, Kharkiv, Kulykivska str. 41- bulk manufacturer, packager, quality control (physicochemical), batch releaser, "PHARMEX GROUP" LLC, 100, Shevchenka str.,08300, Kyiv region, Boryspil, Ukraine- quality control (microbiological)	Ukraine	Zdorovyie Narodu, 61013, Kharkiv Region, Kharkiv, Shevchenko str. 22	Ukraine	PoM
4	14.04.2023	Adione	doxylamine (doxylamine succinate), pyridoxine (pyridoxine hydrochloride)	tablets prolonged-release	10mg+10mg; (30/3x10) in blister	The Madras Pharmaceuticals, 137-B, Old Mahabalipuram Road, Karappakkam, Chennai. Tamilnadu, 603 103	India	CROSS PHARM, S.A, Quai des Bergues 23-1201 Geneva	Switzerland	PoM
5	26.04.2023	Ezo 20	esomeprazole (esomeprazole magnesium)	tablets gastro-resistant	20mg; (30/3x10/) in blister	Ind-Swift ltd., Off NH-21, Village Jawaharpur, Tehsil Dera Bassi, District S.A.S. Nagar (Mohali), Punjab, In-140507	India	Ind-Swift ltd., Off NH-21, Village Jawaharpur, Tehsil Dera Bassi, District S.A.S. Nagar (Mohali), Punjab, In-140507	India	PoM
6	26.04.2023	Ezo 40	esomeprazole (esomeprazole magnesium)	tablets gastro-resistant	40mg; (30/3x10/) in blister	Ind-Swift ltd., Off NH-21, Village Jawaharpur, Tehsil Dera Bassi, District S.A.S. Nagar (Mohali), Punjab, In-140507	India	Ind-Swift ltd., Off NH-21, Village Jawaharpur, Tehsil Dera Bassi, District S.A.S. Nagar (Mohali), Punjab, In-140507	India	PoM

7	26.04.2023	COMBECEN	thiamine (thiamine hydrochloride), riboflavin (riboflavin sodium phosphate), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, nicotinamide	solution for injection	10mg/ml+5mg/ml+5mg/ml+0,2mg/ml+100mg/ml; 100ml glass vial, 250ml glass vial	CEVAVISA, S.L., Cami Pedra Estela, s/n, Reus Tarragona, 43205	Spain	CEVAVISA, S.L., Cami Pedra Estela, s/n, Reus Tarragona, 43205	Spain	PoM
8	12.06.2023	Doktor MOM herbal cough lozenges with raspberry flavor	glycyrrhiza glabra, zingiber officinale, emblica officinalis, levomenthol	lozenges	15mg+10mg+10mg+7mg; (20/4x5) in strip	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Survey No. 101/2 and 102/1, Daman Industrial Estate, Kadaiya, Daman-396 210	India	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC
9	22.06.2023	Mesatone	phenylephrine (phenylephrine hydrochloride)	solution for injection	10mg/ml; (10/1x10) ampoules 1ml in blister	Limited Liability Company «Pharmaceutical Company «Zdorovyе», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Experimental Plant «GNCLS» LLC, 61057, Kharkiv, Vorobyova str., 8	Ukraine	PoM
10	22.06.2023	Enalapril-H-Zdorovyе	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg; (20/1x20) blister	Limited Liability Company «Pharmaceutical Company «Zdorovyе», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovyе», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM
11	22.06.2023	Glibenclamid-Zdorovyе	glibenclamide	tablets	5mg; (50/5x10) in blister	Limited Liability Company «Pharmaceutical Company «Zdorovyе», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovyе», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM
12	22.06.2023	Analgin-Zdorovyе	metamizole (metamizole sodium)	tablets	500mg; (10/1x10) in blister	Limited Liability Company «Pharmaceutical Company «Zdorovyе», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovyе», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	OTC

13	22.06.2023	Digoxin-Zdorovye	digoxin	tablets	0,25mg; (50/1x50/) in blister	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM
14	11.07.2023	Loratadin-Zdorovye	loratadine	tablets	10mg; (10/1x10) in blister	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	OTC
15	11.07.2023	Platyphylline-Zdorovye	platyphylline (platyphylline hydrotartrate)	solution for injection	2mg/ml; (10/1x10) ampoules 1ml in blister	Pharmaceutical Company «Zdorovye» LLC, 61013, Kharkov, Shevchenko str., 22	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM
16	11.07.2023	Phenilin-Zdorovye	phenindione	tablets	30mg; (20/1x20) in blister	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM
17	11.07.2023	Gentamicin-Zdorovye	gentamicin (gentamicin sulfate)	solution for injection	40mg/ml; (10) ampoules 2ml, (10/2x5) ampoules 2ml in blister	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM

18	11.07.2023	Sennosides 7,5mg tablets	calcium sennosides (hydroxyanthracene glycosides sennosides B)	tablets	7,5mg; (100/10x10/) in blister	Akriti Pharmaceuticals Pvt. Ltd., D-10, D-11, MIDC, Jejuri-Nira Road, Jejuri, Taluka Purandar, Dist-Pune 412 303, Maharashtra	India	Akriti Pharmaceuticals Pvt. Ltd., Office No.205, Thane mint, Indiabulls, Behind Hiranandani Meadows. Near Hyde Park, off. Gladys Alvaris Road, Thane (W)400610, Maharashtra	India	OTC
19	11.07.2023	Zvezdochka Flu	paracetamol, pheniramine (pheniramine maleate), phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	325mg+20mg+10mg+50mg (10) sachets 15g	Danapha Pharmaceutical JSC, 253 Dung Si Thanh Khe str., Thanh Khe District, Danang city	Vietnam	«DOMINANTA-SERVIS» JSC, Komsomolskaya St. 1, building 49, room 1, apartment 223, Podolsk, Moscow region, 142100	Russia	OTC
20	21.07.2023	Senadexin-Zdorovye	sennosides A, B	tablets	70mg; (10) in blister	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	OTC
21	21.07.2023	Adrenalin-Zdorovye	adrenaline (adrenaline tartrate)	solution for injection	1,82mg/ml; (10/1x10/) ampoules 1ml in blister	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM
22	21.07.2023	Anaprilin-Zdorovye	propranolol (propranolol hydrochloride)	tablets	10mg; (50/5x10) in blister	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM

23	21.07.2023	Anaprilin-Zdorovye	propranolol (propranolol hydrochloride)	tablets	40mg; (50/5x10) in blister	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company «Pharmaceutical Company «Zdorovye», 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM
24	25.08.2023	Omnopon-ZN	morphine (morphine hydrochloride), noscapine, papaverine (papaverine hydrochloride), codeine, thebaine	solution for injection	11,5mg/ml+5,4mg/ml+0,72mg/ml+1,44mg/ml+0,1mg/ml; (100/20x5) ampoules 1ml in blister	Limited Liability Company «Kharkiv Pharmaceutical Enterprise «Zdorovye Narodu», 61002, Kharkiv, Kulykivska str. 41	Ukraine	Limited Liability Company «Kharkiv Pharmaceutical Enterprise «Zdorovye Narodu», 61013, Kharkiv Region, Kharkiv, Shevchenko str. 22	Ukraine	PoM/UC
25	25.08.2023	Ena-Denk 10	enalapril (enalapril maleate)	tablets	10mg; (30/3x10) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, quality control (physicochemical), batch releaser, Swiss Caps GmbH, Grassingerstrasse 9, 83043, Germany- packager, LSSE & Co. KG, Mangelsfeld 4, Bad Bocklet-Grossenbrach, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM
26	25.08.2023	Ena-Denk 20	enalapril (enalapril maleate)	tablets	20mg; (30/3x10) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, quality control (physicochemical), batch releaser, Swiss Caps GmbH, Grassingerstrasse 9, 83043, Germany- packager, LSSE & Co. KG, Mangelsfeld 4, Bad Bocklet-Grossenbrach, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM

27	06.09.2023	Zvezdochka Noz	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 15ml glass vial with dispenser device	Danapha Pharmaceutical JSC, 253 Dung Si Thanh Khe str., Thanh Khe District, Danang city	Vietnam	«DOMINANTA-SERVIS» JSC, Komsomolskaya St. 1, building 49, room 1, apartment 223, Podolsk, Moscow region, 142100	Russia	OTC
28	05.10.2023	Neodex	neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate), dexamethasone (dexamethasone sodium micrinized sterile)	drops eye	1,0mg/ml+6000IU/ml+5,0mg/ml; 5ml plastic vial with dropper	Egyptian International Pharmaceutical Industries Company (EIPICO), First industrial area B1-P.O. 10th of Ramadan City	Egypt	Egyptian International Pharmaceutical Industries Company (EIPICO), First industrial area B1-P.O. 10th of Ramadan City	Egypt	PoM
29	05.10.2023	Novex Ibuprofen	ibuprofen	suspension oral	20mg/ml; glass bottle 120ml	Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad	Pakistan	Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad	Pakistan	OTC
30	24.10.2023	Swiftpime	cefepime (cefepime hydrochloride)	powder for solution for injection	1000mg; glass vial 20ml	Ind-Swift Limited, Plot no 11, Industrial Area, Katha-Batholikalan, Baddi, District-Solan, H.P. 173205	India	Ind-Swift Limited, Off. NH-21, Village Jawaharpur, Tehsil Derabassi, District SAS Nagar (Mohali), Punjab-140507	India	PoM
31	24.10.2023	Quifol	propofol	emulsion for injection	10mg/ml; (10/10x1) glass vials 20ml in blister	Aculife Healthcare Private Limited, Unit-5, IDP, Village-Sachana, Tal.-Viramgam, Dist.-Ahmedabad, Gujarat, 382150	India	Aculife Healthcare Private Limited, Commerce House- V, Besides Vodafone House, Prahladnagar Corporate Road, Ahmedabad, Gujarat, 380051	India	PoM
32	13.11.2023	Cefoswift	cefoperazone (cefoperazone sodium), sulbactam (sulbactam sodium)	powder for solution for injection	1000mg+500mg; glass vial 20ml	Ind-Swift Limited C/o Shamsree Lifesciences Limited Plot no 11, Industrial area Katha-Batholikalan, Baddi, District-Solan H.P., 173205	India	Ind-Swift Limited, Global Business Unit, Jawaharpur, OffNH 21, Derabassi, Distt. Mohali, Punjab, 14507	India	PoM
33	07.11.2023	Ena+HCT-Denk 20/12,5	enalapril (enalapril maleate), hydrochlorothiazide	tablets	20mg+12,5mg; (30/3x10) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM

34	30.11.2023	Atracurium Besylate 10mg/ml	atracurium (atracurium besylate)	solution for injection	50mg/5ml; (5) ampoules 5ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kwaliti Pharma- ceuticals Ltd , Plot No. 1-A Industrial Area, Raja Ka Bagh, Tehsil Nurpur, district Kangra, Himachal Pradesh, India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM
35	30.11.2023	Atracurium Besylate 10mg/ml	atracurium (atracurium besylate)	solution for injection	25mg/2,5ml; (5) ampoules 3ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kwaliti Pharma- ceuticals Ltd , Plot No. 1-A Industrial Area, Raja Ka Bagh, Tehsil Nurpur, district Kangra, Himachal Pradesh, India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM