

Rejection for registration (2016)

N	Date	Trade name	International non-proprietary (generic) names or names of active substances	Dosage form	Dosage strength & output form (packaging)	Manufacturer
1	04.02.2016	For Hair and Nails	vitamin B1, calcium, pantothenate, paraaminobenzoic acid, yeast, L-cystine, hydrolysed keratin	capsules	60mg+60mg+30mg+130mg+20mg+20mg; (30/3x10/), in blister	Amoun Pharmaceutical Company, 1 st Industrial Zone, El-Obour City, Cairo
2	04.02.2016	Capto 25	captopril	tablets	25mg; (400/10x4x10/) in blister	Tuton Pharmaceuticals, 85, GIDC, Industrial estate Naroda, Ahmedabad, Gujarat
3	04.02.2016	Captopril 50	captopril	tablets	50mg; (400/10x4x10/), in blister	Tuton Pharmaceuticals, 85, GIDC, Industrial estate Naroda, Ahmedabad, Gujarat
4	04.02.2016	Terbinafine tablets 250mg	terbinafine (terbinafine hydrochloride)	tablets	250mg; (100/10x10/), in blister	Tuton Pharmaceuticals, 85, GIDC, Industrial estate Naroda, Ahmedabad, Gujarat
5	04.02.2016	Enalapril maleate and hydrochlorothiazide	enalapril maleate, hydrochlorothiazide	tablets	10mg+25mg (100/10x10/), in blister	Tuton Pharmaceuticals, 85, GIDC, Industrial estate Naroda, Ahmedabad, Gujarat

6	04.02.2016	Prilonest	prilocaine (prilocaine hydrochloride), felypressin	solution for injection	30mg/ml+0,03IU/ml; (50) cartridges 1.8ml	DFL Industria e Comercio S.A., Estrada do Guerengue, 2059, Jacarepagua, Rio de Janeiro-RJ
7	26.02.2016	Betahistine- Ratiopham	betahistine (betahistine dihydrochloride)	tablets	24mg; (20/2x10/), in blister	Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren-batch releaser, Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1 and 2, 73614, Schorndorf-bulk manufacturer, Merckle GmbH, Graf-Arco-Strasse 3, 89079 Ulm, Germany-packager
8	26.02.2016	Betahistine- Ratiopham	betahistine (betahistine dihydrochloride)	tablets	16mg; (30/3x10/), in blister	Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren-batch releaser, Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1 and 2, 73614, Schorndorf-bulk manufacturer, Merckle GmbH, Graf-Arco-Strasse 3, 89079 Ulm, Germany-packager

9	26.02.2016	Ketotifen	ketotifen (ketotifen hydrofumarate)	tablets	1mg; (30/2x15/), in blister	Warsaw Pharmaceutical Works "Polfa" S.A., Karolkowa 22/24 str., 01-207 Warsaw
10	26.02.2016	Zoledronic acid-Teva	zoledronic acid	concentrate for solution for infusion	4mg/5ml; (1), (4), (10) vial	Pliva Hrvatska d.o.o., Prilaz baruna Filipovica 25, Zagreb 10000
11	26.02.2016	Zoledronic acid-Teva	zoledronic acid	concentrate for solution for infusion	4mg/5ml; (1), (4), (10) vial	Teva Pharmaceutical Works Private Limited Company, H- 2100 Godollo, Tancsics Mihaly ut 82
12	02.04.2016	Doxolek	doxorubicin (doxorubicin hydrochloride)	solution for i/m injection	2mg/ml; (1) glass vial 5ml	Pharmstandard -Biolik PJSC, 61070, Kharkov, Pomerki-batch releaser, secondary packager, Onco Generix LLC, 83030, Donetsk ,Tambovskaya str. 2, Ukraine-bulk manufacturer, primary packager
13	02.04.2016	Furosemide	furosemide	tablets	40mg; (50/5x10/), in blister	Irbitskiy himfarmzavod JSC, 643 RU, Irbit, St. Sverdlovsk, K. Marksa str., 124

14	02.04.2016	IVEREX PLUS	ivermectin, clorsulon	solution for injection	10mg/ml+100mg/ml; (1) glass vial 10ml, 50ml and 100ml	Credence Remedies Pvt.Ltd., Village Lalpur, Kichha Road, Udham Singh Nagar, Uttarakhand
15	02.04.2016	Introvit-E-Selen	vitamin E, sodium selenite	solution for i/m or s/c injection	50mg/ml+0,5mg/ml; 100ml glass bottle	Interchemie werken De Adelaar Eesti AS, Vanapere tee 14, Viimsi, Harju county- bulk manufacturer, primary packager, batch releaser, Interchemie werken De Adelaar B.V., Metaalweg 8, 5804 CG Venray, the Netherlands- secondary packager
16	02.04.2016	Tamoxifen	tamoxifen (tamoxifen citrate)	tablets	10mg; (30/1x30/), in blister	Ozon Ltd, 445351, Samara dist., Jigulievsk, str. Gydrostroiteley, b.6, b.1, 6-A
17	02.04.2016	Tamoxifen	tamoxifen (tamoxifen citrate)	tablets	20mg; (30/1x30/), in blister	Ozon Ltd, 445351, Samara dist., Jigulievsk, str. Gydrostroiteley, b.6, b.1, 6-A

18	02.04.2016	Paracetamol-Nika	paracetamol	solution for infusion	10mg/ml; 50ml, 100ml, 200ml, in glass bottle	Nika Pharmaceutica Ltd, Zavodskaya Str.1, office 33, Alba Settlement, Nesvizh District, Minsk Region 222603- batch releaser, secondary packager, Nesvizh Plant of Medical Preparations OJSC, Zavodskaya Str. 1, Alba Settlement, Nesvizh District, Minsk Region, 222603, Belarus- bulk manufacturer, primary packager
19	19.04.2016	Artrum	ketoprofen	tablets prolonged- release	150mg; (20/2x10/), in blister, (30/3x10/), in blister	Biosintez OJSC, Druzhby st. 4, 440033, Penza
20	19.04.2016	Carvedilol	carvedilol	tablets	25mg; (30/3x10/), in blister	Medicamen Biotech Ltd.,SP- 1192, A&B, Phase-4, Industrial Area, Bhiwadi, Distt. Alwar, Rajasthan 301019
21	19.04.2016	Lactofiltrum	lignin, lactulose	tablets	355mg+120mg; (30/2x15/), in blister, (60/4x15/), in blister	“AVVA RUS” OJSC, Kirov region, Kirov, Luganskaya str. 56a

22	12.05.2016	Buparvaquone	buparvaquone	solution for i/m injection	50mg/ml; 20ml, 40ml, 50ml glass vial	Intracin Pharmaceutical Pvt Ltd, C-1, B-53,G.I.D.C. Estate, Nadiad.387001 Gujarat
23	12.05.2016	Ozotron-4	ondansetron (ondansetron hydrochloride)	tablets film-coated	4mg; (100/2x50/), in blister	Ozone Pharmaceuticals Ltd, E.P.I.P., Amingaon, Guwahati-731 031, Assam
24	12.05.2016	Moxbro 500	amoxicillin (amoxicillin trihydrate), bromhexine (bromhexine hydrochloride)	capsules	500mg+8mg; (250/25x10/), in blister	Coral Laboratories Ltd, Plot No. 27/28, Pharmacity, Selaqui, Dehradun, Uttarakhand-248 197
25	12.05.2016	Floxatac	ofloxacin	tablets	200mg; (10/1x10/), in blister	Alice Medicare Pvt Ltd, Bhagwanpur, Roorkee, Uttarakhand
26	12.05.2016	Azotac 500	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3), in blister	Alice Medicare Pvt Ltd, Bhagwanpur, Roorkee, Uttarakhand
27	12.05.2016	Levocor	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg; (30/3x10/), in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210

28	12.05.2016	Prolongin	enoxaparin (enoxaparin sodium)	solution for injection	20mg/0.2ml; (1) pre-filled syringe 0.2ml	Shenzhen Techdow Pharmaceutical Co., Ltd., Gaoxinhongyi Road, Nanshan District, Shenzhen, Guangdong Province
29	12.05.2016	Prolongin	enoxaparin (enoxaparin sodium)	solution for injection	40mg/0.4ml; (1) pre-filled syringe 0.4ml	Shenzhen Techdow Pharmaceutical Co., Ltd., Gaoxinhongyi Road, Nanshan District, Shenzhen, Guangdong Province
30	12.05.2016	Prolongin	enoxaparin (enoxaparin sodium)	solution for injection	60mg/0.6ml; (1) pre-filled syringe 0.6ml	Shenzhen Techdow Pharmaceutical Co., Ltd., Gaoxinhongyi Road, Nanshan District, Shenzhen, Guangdong Province
31	12.05.2016	Prolongin	enoxaparin (enoxaparin sodium)	solution for injection	80mg/0.8ml; (1) pre-filled syringe 0.8ml	Shenzhen Techdow Pharmaceutical Co., Ltd., Gaoxinhongyi Road, Nanshan District, Shenzhen, Guangdong Province
32	12.05.2016	Terbinafine hydrochloride cream	terbinafine (terbinafine hydrochloride)	cream	10mg/g; 10g laminated tube	Tuton Pharmaceuticals, 85, GIDC, Industrial estate Naroda, Ahmedabad, Gujarat

33	12.05.2016	Folicor Tablets	folic acid	tablets	5mg; (500/50x10/), in blister, (1000/100x10/), in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210
34	12.05.2016	D.F.O. Gel	diclofenac diethylamine, linseed oil	gel	1.16mg/g+3mg/g; 30g tube	Ozone Pharmaceuticals Ltd, E.P.I.P., Amingaon, Guwahati- 731 031, Assam
35	12.05.2016	Fam H2 40	famotidine	tablets	40mg; (350/5x70/), in blister	Ozone Pharmaceuticals Ltd, E.P.I.P., Amingaon, Guwahati- 731 031, Assam
36	12.05.2016	Fam H2 20	famotidine	tablets	20mg; (350/5x70/), in blister	Ozone Pharmaceuticals Ltd, E.P.I.P., Amingaon, Guwahati- 731 031, Assam
37	12.05.2016	Minon	milrinone	solution for injection	1mg/ml; (1) 10ml glass vial	Coral Laboratories Ltd.5, 6 Khokhani Industrial Complex no. 2, Near Sai Temple, Sativali, Vasai (E), Dist.Thane 401208
38	24.05.2016	Pantoprazol-40	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro- resistant	40mg; (100/10x10/), in strip	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210

39	24.05.2016	Corzit 500 Tablets	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/), in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210
40	24.05.2016	TELITHRO 100	levothyroxine (levothyroxine sodium)	tablets	100mcg; (100/10x10/), in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210
41	24.05.2016	TELITHRO 50	levothyroxine (levothyroxine sodium)	tablets	50mcg; (100/10x10/), in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210
42	24.05.2016	Ciplone-500	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10/), in blister	Alice Medicare Pvt Ltd, Bhagwanpur, Roorkee, Uttarakhand
43	24.05.2016	Cilom-SB	ampicillin (ampicillin sodium), sulbactam	powder for solution for injection	1000mg+500mg; (1) glass vial	Alice Medicare Pvt Ltd, Bhagwanpur, Roorkee, Uttarakhand
44	24.05.2016	Cilom-SB	ampicillin (ampicillin sodium), sulbactam	powder for solution for injection	2000mg+1000mg; (1) glass vial	Alice Medicare Pvt Ltd, Bhagwanpur, Roorkee, Uttarakhand
45	24.05.2016	Omezole-20	omeprazole	capsules	20mg (30/3x10/), in blister	Gracure Pharmaceuticals Ltd., E-1105, Industrial Area, Phase-III, Bhiwadi, Rajasthan

46	24.05.2016	Enrofloxa-cin injection	enrofloxacin	solution for injection	100mg/ml; 30ml, 50ml, 100ml vial	Intracin Pharmaceutical Pvt Ltd, C-1, B-53,G.I.D.C. Estate, Nadiad.387001 Gujarat
47	24.05.2016	Ozovas 20	atorvastatin (atorvastatin calcium)	tablets film-coated	20mg; (50/5x10/), in blister	Ozone Pharmaceuticals Ltd, E.P.I.P., Amingaon, Guwahati-731 031, Assam
48	24.05.2016	Ozovas 10	atorvastatin (atorvastatin calcium)	tablets film-coated	10mg; (50/5x10/), in blister	Ozone Pharmaceuticals Ltd, E.P.I.P., Amingaon, Guwahati-731 031, Assam
49	24.05.2016	Xflocin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	250mg; (100/10x10/), in blister	Medicamen Biotech Ltd.,SP-1192, A&B, Phase-4, Industrial Area, Bhiwadi, Distt. Alwar, Rajasthan 301019
50	24.05.2016	Xflocin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (100/10x10/), in blister	Medicamen Biotech Ltd.,SP-1192, A&B, Phase-4, Industrial Area, Bhiwadi, Distt. Alwar, Rajasthan 301019
51	08.06.2016	Omax-20	omeprazole	capsules	20mg; (30/3x10/) in blister	Biomedicare (India) Pvt. Ltd., H-2/102 Suneja Chamber, Alaknanda Commercial Complex, New Delhi- 110 019

52	22.06.2016	Ibuprofen Denk 400	ibuprofen	tablets film-coated	400mg; (100/10x10/), in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning
53	22.06.2016	Ibuprofen Denk 600	ibuprofen	tablets film-coated	600mg; (20/2x10/), in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning
54	22.06.2016	Donataxel	docetaxel	concentrate for solution for infusion	20mg/0,5ml; (1) glass vial 0.5ml and 1.83ml glass vial with solvent	Laboratorios IMA S.A.I.C., Palpa 2862, Ciudad Autonoma De Buenos Aires
55	22.06.2016	Donataxel	docetaxel	concentrate for solution for infusion	80mg/2ml; (1) glass vial 2ml and 7.32ml glass vial with solvent	Laboratorios IMA S.A.I.C., Palpa 2862, Ciudad Autonoma De Buenos Aires
56	22.06.2016	Ivermectin and clorsulon	ivermectin, clorsulon	solution for injection	10mg/ml+100mg/ml; 10ml, 20ml, 50ml, 100ml glass vial	Intracin Pharmaceutical Pvt Ltd, C-1, B-53,G.I.D.C. Estate, Nadiad.387001 Gujarat
57	22.06.2016	Zerox-500	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (30/3x10/), in strip	Ozone Pharmaceuticals Ltd, E.P.I.P., Amingaon, Guwahati- 731 031, Assam
58	22.06.2016	Zerox-250	azithromycin (azithromycin dihydrate)	tablets film-coated	250mg; (60/6x10), in strip	Ozone Pharmaceuticals Ltd, E.P.I.P., Amingaon, Guwahati- 731 031, Assam

59	04.07.2016	TOP SPOT ON STRONGER	permethrin	solution for external use	650mg/ml; (50) pastic tube-dropper 1ml	BIOVETA a.s., Komenskeho 212/12, 683 23 Ivanovice na Hane
60	04.07.2016	Multivit Mineral	vitamin A, cholecalciferol, vitamin E, thiamine, riboflavin, pyridoxine, cyanocobalamin, dexpanthenol, nicotinic acid, inositol, methionine, cholin dihydrogencitrate, magnesium hypophosphite, cobalt chloride, copper (copper sulfate), zinc (zinc sulfate)	solution for injection	50000IU/ml+25000IU/ml+4mg/ml+10mg/ml+0.04mg/ml+2mg/ml+0.01mg/ml+2mg/ml+5mg/ml+2mg/ml+5mg/ml+5mg/ml+1mg/ml+0.02mg/ml+0.1mg/ml+0.1mg/ml; glass vial 100ml, plastic container 250ml	BIOVETA a.s., Komenskeho 212/12, 683 23 Ivanovice na Hane
61	04.07.2016	Gabaid 100	gabapentin	capsules	100mg; (30/3x10/) in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210
62	04.07.2016	Dexamethasone	dexamethasone (dexamethasone sodium phosphate)	solution for injection	4mg/ml; (5) ampoules 1ml, (10) ampoules 1ml, (5) ampoules 1ml, in blister, (10/2x5/) ampoules 1ml, in blister	Pharmaceutical Company "Zdorovye" LLC, str. Shevchenko, 22, Kharkov
63	04.07.2016	Ornidazole-Nika	ornidazole	solution for infusion	5mg/ml; 50ml glass bottle, 100ml glass bottle, 200ml glass bottle	Nika Pharmaceftica Ltd, Zavodskaya Str. 1, office 33, Alba Settlement, Nesvizh District, Minsk Region 222603

64	20.07.2016	Clarazole	ketoconazole	shampoo	20mg/ml; 100ml plastic container	Medpharma Pharm . & Chem. Inds LLC, Sharjah, Industrial Area 13, P.O. Box: 25235
65	20.07.2016	Ornidazole-Nika	ornidazole	solution for infusion	5g/ml; 50ml plastic container, 100ml plastic container	Nika Pharmaceutica Ltd., Zavodskaya Str. 1, office 33, Alba Settlement, Nesvizh District, Minsk Region 222603-secondary packager, batch releaser (bulk manufacturer, primary packager-Nesvizh Plant of Medical Preparations OJSC, Zavodskaya Str. 1, Alba Settlement, Nesvizh District, Minsk region, 22603, Belarus)
66	20.07.2016	Pantotis	pantoprazole (pantoprazole sodium)	powder lyophilized for solution for injection	40mg; glass vial	PT. Bernofarm, Jl. Gatot Subroto No68, Benjarkemantren Km.18, Buduran-Sidoarjo 61252
67	20.07.2016	Levovid	levofloxacin (levofloxacin hemihydrate)	solution for infusion	5mg/ml; glass bottle 100ml	PT. Bernofarm, Jl. Gatot Subroto No68, Benjarkemantren Km.18, Buduran-Sidoarjo 61252

68	20.07.2016	Glucoryl	glimepiride	tablets	3mg; (30/3x10/) in blister	PT. Bernofarm, Jl. Gatot Subroto No68, Benjarkemantren Km.18, Buduran-Sidoarjo 61252
69	20.07.2016	Midazolam Injection	midazolam	solution for infusion	1mg/ml; ampoule 2ml	Yichang Humanwell Pharmaceutical Co., Ltd, No 19, Dalian Road, Yichang Developing Zone, Yichang, Hubei
70	20.07.2016	Midazolam Injection	midazolam	solution for infusion	5mg/ml; ampoule 2ml	Yichang Humanwell Pharmaceutical Co., Ltd, No 19, Dalian Road, Yichang Developing Zone, Yichang, Hubei
71	20.07.2016	Hexoral Tabs Classic	amylmetacresol, dichlorobenzyl alcohol	tablets orodispersible (with lemon flavour)	0,6mg+1,2mg; (8/2x4/) in strip, (12/3x4/) in strip, (16/4x4/) in strip, (16/2x8/) in strip, (24/3x8) in strip	Unique Pharmaceutical Laboratories (a division of J B Chemicals & Pharmaceuticals Ltd.), Survey No101/2 & 102/1, G.I.D.C. Daman Industrial Estate, Kadaiya, Daman: 396 210

72	20.07.2016	Hexoral Tabs Classic	amylmetacresol, dichlorobenzyl alcohol	tablets orodispersible (with honey-lemon flavour)	0,6mg+1,2mg; (8/2x4) in strip, (12/3x4/) in strip, (16/4x4/ in strip, (16/2x8/) in strip, (24/3x8/) in strip	Unique Pharmaceutical Laboratories (a division of J B Chemicals & Pharmaceuticals Ltd.), Survey No101/2 & 102/1, G.I.D.C. Daman Industrial Estate, Kadaiya, Daman: 396 210
73	20.07.2016	Hexoral Tabs Classic	amylmetacresol, dichlorobenzyl alcohol	tablets orodispersible (with orange flavour)	0,6mg+1,2mg; (8/2x4) in strip, (12/3x4/) in strip, (16/4x4/) in strip, (16/2x8/) in strip, (24/3x8/) in strip	Unique Pharmaceutical Laboratories (a division of J B Chemicals & Pharmaceuticals Ltd.), Survey No101/2 & 102/1, G.I.D.C. Daman Industrial Estate, Kadaiya, Daman: 396 210
74	20.07.2016	Hexoral Tabs Classic	amylmetacresol, dichlorobenzyl alcohol	tablets orodispersible (with blackcurrant flavour)	0,6mg+1,2mg; (8/2x4/) in strip, (12/3x4/) in strip, (16/4x4/) in strip, (16/2x8/) in strip, (24/3x8/) in strip	Unique Pharmaceutical Laboratories (a division of J B Chemicals & Pharmaceuticals Ltd.), Survey No101/2 & 102/1, G.I.D.C. Daman Industrial Estate, Kadaiya, Daman: 396 210
75	20.07.2016	Remifentanil hydrochloride	remifentanil (remifentanil hydrochloride)	powder for solution for injection	1mg; glass vial	Yichang Humanwell Pharmaceutical Co., Ltd, No 19, Dalian Road, Yichang Developing Zone, Yichang, Hubei

76	20.07.2016	Remifentanil hydrochloride	remifentanil (remifentanil hydrochloride)	powder for solution for injection	2mg; glass vial	Yichang Humanwell Pharmaceutical Co., Ltd, No 19, Dalian Road, Yichang Developing Zone, Yichang, Hubei
77	20.07.2016	Clartacor 500mg Tablets	clarithromycin	tablets film-coated	500mg; (10/1x10/) in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210
78	20.07.2016	Dynapar Gel	linseed oil, diclofenac diethylamine, methyl salicylate, menthol	gel	30mg/g+11.6mg/g+10mg/g+50 mg/g; plastic tube	Troikka Pharmaceutical Limited, Commerce House, Satya Marg, Bodakdev, Ahmedabad-380054
79	20.07.2016	Zeltine MR	gliclazide	tablets	60mg; (28/2x14) in blister	Stallion Laboratories Pvt. Ltd, CIB 305/2-3 3-4, G.I.D.C. Kerala (Bavla)Dist: Ahmedabad, Gujarat f
80	20.07.2016	Glistal M2	glimepiride, metformin (metformin hydrochloride)	tablets film-coated	2mg+500mg; (100/10x10/)in blister	Stallion Laboratories Pvt. Ltd, CIB 305/2-3 3-4, G.I.D.C. Kerala (Bavla)Dist: Ahmedabad, Gujarat
81	23.08.2016	Phenybut	phenybut	tablets	250mg; (10/1x10/), in blister, (20/2x10/), in blister, (50/5x10/), in blister	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30

82	23.08.2016	Metpure XL-50	metoprolol (metoprolol succinate)	tablets prolonged release film-coated	50mg	Emcure Pharmaceuticals Ltd., Lane No. 3, Phase II, SIDCO Industrial Complex, Bari- Brahmana, Jammu (J&K)-181 133
83	23.08.2016	L-Quin	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg; (10/1x10/) in blister	Alice Medicare Pvt Ltd, Bhagwanpur, Roorkee, Uttarakhand
84	23.08.2016	Protamine	protamine (protamine hydrochloride)	solution for injection	1000IU/ml; (5) ampoules 5ml	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg- batch releaser, Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, CH-4127, Birsfelden, Switzerland- bulk manufacturer, packager
85	15.09.2016	Rastan	somatropin	powder lyophilized for solution for s/c injection	4IU (1,33mg); glass vial with powder and 1ml glass vial with solvent, in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28
86	06.10.2016	Brovaseptol	norsulfazole, sulgine, trimethoprim, oxytetracycline (oxytetracycline hydrochloride), tylosin (tylosin tartrate)	powder oral	80mg/g+70mg/g+30mg/g+45mg/g+25mg/g; 100g plastic container, 500g plastic container	Brovafarma Ltd,18-a, Nezalezhnosti blvd., Brovary, Kyiv region, 07400

87	06.10.2016	Brovermec-tin	ivermectin	solution for injection	10mg/ml; (10) ampoules 1ml, 10ml glass vial, 20 glass vial, 50ml glass vial, 100ml glass vial	Brovafarma Ltd,18-a, Nezalezhnosti blvd., Brovary, Kyiv region, 07400
88	06.10.2016	Vagimilt	clindamycin (clindamycin phosphate), clotrimazole	capsules vaginal	100mg+100mg; (7/1x7/) in blister	SOFTGEL HEALTHCARE PVT Ltd, Survey No.20/1, Vandalur-Kelambakkam Road, Pudupakkam Village, Kancheepuram District 603 103, Tamilnadu
89	10.11.2016	Ecotrixon	ceftriaxone (ceftriaxone sodium)	powder for solution for injection	1000mg; (1) glass vial and 10ml solvent in ampoule	PT. Bernofarm, Jl. Gatot Subroto No68, Banjarkemantren Km.18, Buduran-Sidoarjo 61252
90	10.11.2016	Diclonerive	diclofenac (diclofenac sodium), thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin	capsules	50mg+50mg+50mg+0,25mg; (10/1x10/), (20/2x10/) and (30/3x10/) in strip	Adwia Pharmaceuticals,10th of Ramadan City, Industrial Area A-2
91	10.11.2016	C-Kof	adhatoda vasica, glycyrrhiza glabra, ocimum sanctum, solanum xanthocarpum, apis mellifera, piper longum, zingiber officinale, mentha piperita	syrup	250mg/5ml+250mg/5ml+200mg/5ml+200mg/5ml+200mg/5ml+50mg/5ml+40mg/5ml+1mg/5ml;100ml plastic bottle and 10ml measuring cup	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210

92	10.11.2016	Wencon-150	fluconazole	tablets	150mg; (20/2x10/) in blister	Wens Formulation, 5 Calico Nagar, Narol Ahmedabad, Gujarat
93	10.11.2016	Wencon-200	fluconazole	tablets	200mg (20/2x10/) in blister	Wens Formulation, 5 Calico Nagar, Narol Ahmedabad, Gujarat
94	10.11.2016	Nimosul	nimesulide	tablets	100mg; (100/10x10/) in blister	Wens Formulation, 5 Calico Nagar, Narol Ahmedabad, Gujarat
95	10.11.2016	Omezole-20	omeprazole	capsules	20mg; (100/10x10/) in strip	Wens Formulation, 5 Calico Nagar, Narol Ahmedabad, Gujarat
96	10.11.2016	Azicin-500	azithromycin	tablets film-coated	500mg; (3/1x3/) in blister	Wens Formulation, 5 Calico Nagar, Narol Ahmedabad, Gujarat
97	10.11.2016	Azicin-250	azithromycin	tablets film-coated	250mg; (6/1x6/) in strip	Wens Formulation, 5 Calico Nagar, Narol Ahmedabad, Gujarat
98	10.11.2016	Ketlac	ketorolac (ketorolac tromethamine)	tablets film-coated	10mg; (100/10x10/) in blister	Wens Formulation, 5 Calico Nagar, Narol Ahmedabad, Gujarat
99	10.11.2016	Sodium chloride	sodium chloride	solution for infusion	9mg/ml; 100ml, 200ml, 250ml, 400ml, 500ml plastic vial	Kelun-Kazpharm Ltd., Almaty region, Karasaray province, Eltay village area, v. Kokozeck

100	23.11.2016	Erec	sildenafil (sildenafil citrate)	tablets	100mg; (4/1x4/), (12/3x4/), (40/10x4/), (100/25x4/), (400/100x4/), in strip	Adwia Pharmaceuticals, 10th of Ramadan City, Industrial Area A-2 for Adwia, 1st Industrial Area, El Obour City, Cairo, Egypt
101	23.11.2016	Kliran	ondansetron (ondansetron hydrochloride)	solution for injection	2mg/ml; (5) ampoules 4ml	PT. Bernofarm, Jl. Gatot Subroto No68, Banjarkemantren Km.18, Buduran-Sidoarjo 61252
102	08.12.2016	Tirdicef	cefotaxime (cefotaxime sodium)	powder for solution for injection	1000mg; (1) glass vial and 4ml ampoule with solvent	PT. Bernofarm, Jl. Gatot Subroto No68, Banjarkemantren Km.18, Buduran-Sidoarjo 61252
103	08.12.2016	Macef	cefepime (cefepime hydrochloride)	powder for solution for injection	1000mg; (1) glass vial and 10ml solvent in ampoule	PT. Bernofarm, Jl. Gatot Subroto No68, Banjarkemantren Km.18, Buduran-Sidoarjo 61252
104	08.12.2016	ZeOME30-20	omeprazole	capsules delayed-release	20mg; (200/20x10/) in strip	Cotec Healthcare (P) Ltd., N.H.No. 74, Roorkee-Dehradun Highway, Kishanpur, Roorkee, (Uttarakhand)
105	08.12.2016	Toreo Sildenafil Oral Spray	sildenafil	spray oral	18.38mg/ml; 20ml plastic bottle	Laboratorios La Sante S.A., Calle 17A No. 32-34, 10491 Bogota D.C.

106	08.12.2016	Penstrep-400	procaine penicillin G, dihydrostreptomycin (dihydrostreptomycin sulphate)	suspension for injection	200000IU/ml+200mg/ml; 50ml and 100ml glass bottle	Interchemie werken De Adelaar Eesti AS, Vanapere tee 14, Viimsi, Harju county- bulk manufacturer, primary packager, batch releaser, Interchemie werken De Adelaar B.V., Metaalweg 8, 5804 CG Venray, the Netherlands- secondary packager
107	08.12.2016	Imipex	imipenem (imipenem monohydrate), cilastatin (cilastatin sodium)	powder for solution for infusion	500mg+500mg; (1) glass vial	PT. Bernofarm, Jl. Gatot Subroto No68, Banjarkemantren Km.18, Buduran-Sidoarjo 61252
108	08.12.2016	Sulbacef	cefoperazone (cefoperazone sodium), sulbactam (sulbactam sodium)	powder for solution for injection	500mg+500mg; (1) glass vial and 5ml ampoule with solvent	PT. Bernofarm, Jl. Gatot Subroto No68, Banjarkemantren Km.18, Buduran-Sidoarjo 61252
109	19.12.2016	Urostim	lyophilized bacterial lysate (E. coli 29, E. coli J5, Proteus mirabilis, Klebsiella pneumonia, Enterococcus faecalis)	tablets	50mg (3x10 ⁹ bacterial cells+3x10 ⁹ bacterial cells+0.4x10 ⁹ bacterial cells+0.4x10 ⁹ bacterial cells); (10/1x10/) and (30/3x10/) in blister	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi

110	30.12.2016	Azimex	azithromycin (azithromycin dihydrate)	capsules	500mg; (3/1x3/) and (6/2x3/) in blister	Birzeit Pharmaceutical Company (BPC), Ramallah, Industrial Zone, P.O. box 79
111	30.12.2016	Azimex	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6/) in blister	Birzeit Pharmaceutical Company (BPC), Ramallah, Industrial Zone, P.O. box 79
112	30.12.2016	Esdecoq	decoquinat	powder oral	6g; 25kg paper pack	Zhejiang Esigma Animal Health Co., Ltd, 3 Chu Chao Road, Changan Town, Haining City, Zhejiang Province, 314422
113	30.12.2016	Esdol	clopidol	powder oral	25%; 25kg paper pack	Zhejiang Esigma Animal Health Co., Ltd, 3 Chu Chao Road, Changan Town, Haining City, Zhejiang Province, 314422
114	30.12.2016	Esrob	robenidine hydrochloride	powder oral	6,6g; 25kg paper pack	Zhejiang Esigma Animal Health Co., Ltd, 3 Chu Chao Road, Changan Town, Haining City, Zhejiang Province, 314422

115	30.12.2016	Anitid	ranitidine (ranitidine hydrochloride)	solution for injection	25mg/ml; (5) ampoules 2ml	PT. Bernofarm, Jl. Gatot Subroto No68, Banjarkemantren Km.18, Buduran-Sidoarjo 61252
116	30.12.2016	Irriton	-	solution irrigation	500ml plastic pack	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9
117	30.12.2016	Sinogal-Aversi	ampicillin (ampicillin sodium), sulbactam (sulbactam sodium)	powder for solution for i/m and i/v injection	1000mg+500mg; glass vial	Aversi-Rational Ltd, Chirnakhuli str. 14, 0198 Tbilisi
118	30.12.2016	Thymogen	alpha-glutamyl-tryptophan	solution for injection	100mcg/ml; (5) and (10) ampoules 1ml	CYTOMED JSC, 2 Muchnoj line, Saint-Petersburg
119	30.12.2016	Thymogen	alpha-glutamyl-tryptophan	spray nasal	25mcg/dose; 10ml glass vial	CYTOMED JSC, 2 Muchnoj line, Saint-Petersburg
120	30.12.2016	Allocin-alfa	histidyl-glycyl-valyl-seryl-glycyl-histidyl-glycyl-glutaminy-histidyl-glycyl-valyl-histidyl-glycine	powder lyophilized for solution for s/c injection	1mg/ml; (1), (2, (3,) (4), (5), (6, (10), (20) ampoules 1ml	FSI "Russian Cardiology Research and Production Complex" of the Russian Federation Ministry of Health- Experimental production of medical and biological preparations, 121552, Moscow, 3-rd Cherepkovskaya Street, 15A build. 24, 25, 48

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