

Antibiotice 
Science and soul

Product Portfolio

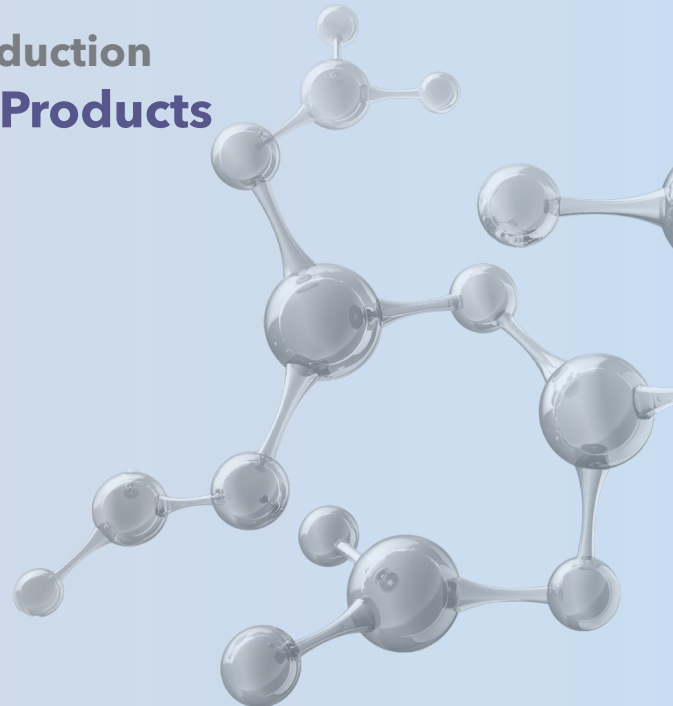
international
reliable partner

EU GMP & US FDA Top manufacturer for
Penicillins - powder for injection

Worldwide leader for
Nystatin APIs

State-of-the-Art production
facility for **Topical Products**

Certified CRO
Contract Research Organization



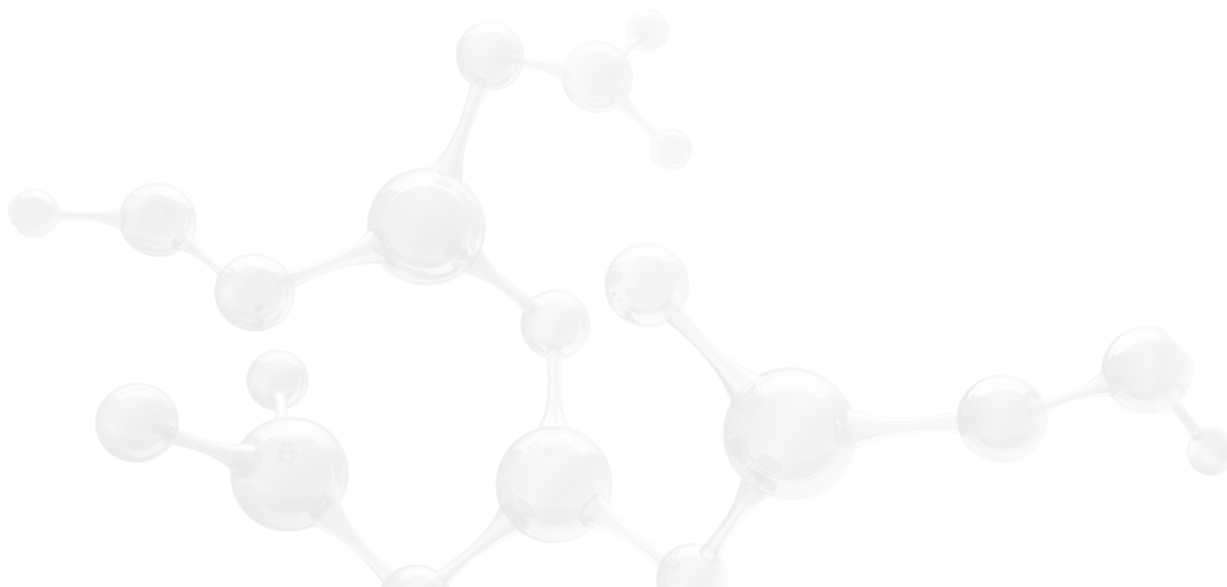
Let's Create **The Future Together!**

” *Following its destiny over the last 67 years, our company started as a traditional manufacturer of Active Ingredients and became a reliable top European Generics Manufacturer.*

Through our business plan The Future Together we have designed our development perspective up until 2030. We start the way to our future destination using our experience, current and future manufacturing capacities, developing generic medicines from Molecule to Market.

*We invite you to join us in building **The Future Together!*** ”

Antibiotic Team



Who we are:

- **US-FDA & EU GMP worldwide leading manufacturer of Nystatin APIs**, also Nystatin API produced by Antibiotice is the reference standard certified by the United States Pharmacopeia
- **EU GMP & US-FDA top manufacturer for penicillins-powders for injection:** penicillins and penicillins in combination with beta-lactam inhibitors
- **20+ years presence in the US market** with Nystatin API and penicillin powders for injection
- One of the most modern **European manufacturing facilities for topical products:** ointments, creams, gels, suppositories and pessaries
- **Manufacturing facilities for various pharmaceutical solid oral forms:** penicillin capsules, cephalosporin capsules, non-penicillin capsules, tablets, film-coated tablets, MR/SR tablets
- **Diversified and customer-focused portfolio of products intended to improve the quality of life:** food supplements, dermocosmetics, medical devices
- **Fully integrated, certified contract research organization (CRO)**, specialized in Phase I Clinical Trials and Bioequivalence studies
- **Presence in 70+ countries worldwide**



EU GMP & US FDA Top Manufacturer for Powders for Injection

penicillin and penicillins
in combination with
beta-lactams inhibitors



- ➔ Ampicillin and Sulbactam
- ➔ Amoxicillin and Clavulanic Acid
- ➔ Ampicillin Sodium
- ➔ Nafcillin Sodium
- ➔ Flucloxacillin Sodium
- ➔ Piperacillin and Tazobactam
- ➔ Benzylpenicillin
- ➔ Benzathine Benzylpenicillin



J – Antiinfectives for systemic use

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
J01 – Antibacterials for systemic use							
1	amoxicillin and clavulanic acid	AMOXIPLUS 1000mg/200 mg	powder for injection/infusion	Augmentin, GSK	Rx	Box x 1 vial Box x 10 vials Box x 25 vials Box x 50 vials Box x 100 vials	EU eCTD
2	ampicillin sodium sulbactam sodium	AMPIPLUS® 1000 mg/ 500 mg	powder for injection	Unasyn, Pfizer	Rx	Box x 1 vial Box x 10 vials Box x 25 vials Box x 50 vials	EU eCTD
3	ampicillin sodium sulbactam sodium	AMPIPLUS® 2000 mg/ 1000 mg	powder for injection	Unasyn, Pfizer	Rx	Box x 1 vial Box x 10 vials	EU eCTD
4	ampicillin sodium	Ampicillin ATB® 250 mg	powder for injection	Doktacillin, Meda AB	Rx	Box x 1 vial Box x 100 vials	EU eCTD
5	ampicillin sodium	Ampicillin ATB® 500 mg	powder for injection	Doktacillin, Meda AB	Rx	Box x 1 vial Box x 100 vials	EU eCTD
6	ampicillin sodium	Ampicillin ATB® 1000 mg	powder for injection	Doktacillin, Meda AB	Rx	Box x 1 vial Box x 50 vials Box x 100 vials	EU eCTD
7	ampicillin sodium	Ampicillin ATB® 2000 mg	powder for injection	Doktacillin, Meda AB	Rx	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	EU eCTD
8	ampicillin sodium	Ampicillin for Injection USP 250 mg	powder for injection	Ampicillin for injection USP Sandoz	Rx	Box x 1 vial Box x 50 vials Box x 100 vials	USeCTD
9	ampicillin sodium	Ampicillin for Injection USP 500 mg	powder for injection	Ampicillin for injection USP Sandoz	Rx	Box x 1 vial Box x 50 vials Box x 100 vials	USeCTD
10	ampicillin sodium	Ampicillin for Injection USP 1 g	powder for injection	Ampicillin for injection USP Sandoz	Rx	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	USeCTD
11	ampicillin sodium	Ampicillin for Injection USP 2 g	powder for injection	Ampicillin for injection USP Sandoz	Rx	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	USeCTD
12	ampicillin sodium sulbactam sodium	Ampicillin and Sulbactam for Injection USP 1.5 g	powder for injection	Unasyn for injection USP, Pfizer	Rx	Box x 1 vial Box x 10 vials Box x 25 vials Box x 50 vials	USeCTD
13	ampicillin sodium sulbactam sodium	AMPICILLIN and Sulbactam for Injection USP 3 g	powder for injection	Unasyn for injection USP, Pfizer	Rx	Box x 10 vials	USeCTD
14	benzathine benzylpenicillin	MOLDAMIN® 1200000 IU	powder for suspension for injection		Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**

** Dossier availability depending on country legislation

J – Antiinfectives for systemic use

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
J01 – Antibacterials for systemic use							
15	ceftriaxone sodium	CEFORT® 250 mg	powder for injection /infusion	Rocephin, Hofmann La Roche	Rx	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
16	ceftriaxone sodium	CEFORT® 500 mg	powder for injection /infusion	Rocephin, Hofmann La Roche	Rx	Box x 1 vial Box x 10 vials Box x 50 vials Box x 100 vials	**
17	ceftriaxone sodium	CEFORT® 1g	powder for injection /infusion	Rocephin, Hofmann La Roche	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
18	ceftriaxone sodium	CEFORT® 2 g	powder for injection /infusion	Rocephin, Hofmann La Roche	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
19	cefotaxime sodium	Cefotaxime ATB® 1g	powder for injection /infusion	Claforan, Lepetit	Rx	Box x 1 vial Box x 10 vials	**
20	ceftazidime pentahydrate	CEFTAMIL® 1 g	powder for injection /infusion	Fortum , Gloxo	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
21	ceftazidime pentahydrate	CEFTAMIL® 2 g	powder for injection /infusion	Fortum , Gloxo	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
22	cefuroxime sodium	Cefuroxime ATB® 750 mg	powder for suspension (im) /injection (iv)	Zinacef, GSK	Rx	Box x 1 vial Box x 10 vials Box x 100 vials	**
23	cefuroxime sodium	Cefuroxime ATB® 1.5 g	powder for suspension (im) /injection (iv)	Zinacef, GSK	Rx	Box x 1 vial Box x 10 vials Box x 100 vials	**
24	colistimethate sodium	Colistin ATB® 1 000 000 IU	powder for injection /infusion		Rx	Box x 1 vial Box x 50 vials Box x 100 vials	in-licensing
25	cefixime	EFICEF® 100 mg	capsules	Oroken, Aventis Cefixoral 400 mg Menarini	Rx	Box x 10 capsules Box x 1000 capsules	**
26	cefixime	EFICEF® 200 mg	capsules	Oroken, Aventis Cefixoral 400 mg Menarini	Rx	Box x 10 capsules Box x 1000 capsules	EU eCTD
27	clarithromycin	ROCLARIN® 500 mg	film coated tablets	Klacid, Viatris	Rx	Box x 20 tablets*	*
28	cycloserine	Cycloserine ATB® 250mgc	apsules	Seromycin, Ely Lilly	Rx	Box x 50 capsules Box x 100 capsules	in-licensing
29	ertapenem sodium	Ertapenem ATB® 1 g	powder for concentrate for solution for infusion	Invanz, Merck Sharp& Dohme	Rx	Box x 10 vials*	*
30	ethambutol hydrochloride	Ethambutol ATB® 250mg, 400mg	film coated tablets	Myambutol, Wyeth	Rx	Box x 20 tablets Box x 1500 tablets	**

** Dossier availability depending on country legislation

J – Antiinfectives for systemic use

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
J01 – Antibacterials for systemic use							
31	ethionamide	Ethionamide ATB® 250 mg	film coated tablets	Trecator ,Wyeth	Rx	Box x 100 tablets	in-licensing
32	flucloxacillin sodium	Flucloxacillin ATB® 500 mg	powder for injection	Floxapen, Aurobindo	Rx	Box x 1 vial Box x 10 vials	EU eCTD
33	flucloxacillin sodium	Flucloxacillin ATB® 1000 mg	powder for injection	Floxapen, Aurobindo	Rx	Box x 1 vial Box x 10 vials	**
34	imipenem monohydrate +cilastatin sodium	Imipenem/Cilastatin ATB® 500 mg/500 mg	powder for infusion	Tienam, MSD	Rx	Box x 1 vial Box x 5 vials Box x 10 vials	in-licensing
35	isoniazid	Isoniazid ATB® 100 mg, 300 mg	tablets	Isozid, Fatol	Rx	Box x 20 tablets Box x 30 tablets Box x 1500 tablets	**
36	levofloxacin	Levofloxacin ATB 250 mg, 500 mg	film coated tablets	Tavanic 500 mg, Sanofi Aventis	Rx	Box x 10 tablets	EU eCTD
37	meropenem trihydrate	Meropenem ATB® 500 mg	powder for injection /infusion	Merrem, Pfizer	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
38	meropenem trihydrate	Meropenem ATB® 1000 mg	powder for injection /infusion	Merrem, Pfizer	Rx	Box x 1 vial Box x 10 vials Box x 50 vials	**
39	nafcillin sodium	Nafcillin for Injection USP 1 g	powder for injection	Nafcillin for Injection USP, Sandoz	Rx	Box x 10 vials	USeCTD
40	nafcillin sodium	Nafcillin for Injection USP 2 g	powder for injection	Nafcillin for Injection USP, Sandoz	Rx	Box x 10 vials	USeCTD
41	oxacillin sodium monohydrate	Oxacillin ATB® 500 mg	powder for injection /infusion		Rx	Box x 1 vial Box x 50 vials Box x 100 vials	*
42	oxacillin sodium monohydrate	Oxacillin ATB® 1 g	powder for injection /infusion		Rx	Box x 1 vial Box x 50 vials Box x 100 vials	*
43	piperacillin sodium tazobactam sodium	PERASIN® 2.5 g	powder for solution for infusion	Tazocin, Pfizer	Rx	Box x 1 vial Box x 10 vials	EU eCTD
44	piperacillin sodium tazobactam sodium	PERASIN® 4.5 g	powder for solution for infusion	Tazocin, Pfizer	Rx	Box x 1 vial Box x 10 vials	EU eCTD
45	pyrazinamide	Pyrazinamide ATB® 500 mg	tablets	Zinamide, MSD	Rx	Box x 20 tablets Box x 1500 tablets	**
46	rifampicin + isoniazid	SINERDOL® ISO	capsules		Rx	Box x 10 capsules Box x 1000 capsules	**
47	rifampicin	SINERDOL® 150 mg, 300 mg	capsules		Rx	Box x 10 capsules Box x 20 capsules Box x 1000 capsules	**
48	tigecycline	Tigeclycin ATB® 50 mg	powder for infusion	Tygacil, Pfizer	Rx	Box x 1 vial Box x 10 vials	in-licensing

* Dossier with limited production and/or regulatory support

** Dossier availability depending on country legislation

New State-of-the-Art Manufacturing Facility for Topical Products

More than 67 years of Experience
in Manufacturing Topical Products



Dedicated Manufacturing Lines:

➔ 2 lines for ointments, creams and gels

➔ 2 lines for suppositories and pessaries

 SUSTAINABLE DEVELOPMENT GOALS



→ 4 dedicated manufacturing lines:

- **2 manufacturing lines for ointments, creams, gels and cutaneous pastes**

Aluminum tubes, \varnothing 13 - 35 mm; fill volume: from 6 to 150 g of product;

Plastic/laminated tubes, \varnothing 25 - 35 mm; fill volume: from 100 to 150 g of product; with the possibility of expansion to smaller weights.

- **2 manufacturing lines for suppositories and pessaries**

Suppositories, fill volume: from 1 to 2.3 g, using PVC/PE and Alu/PE foil as primary packaging;

Pessaries, fill volume: from 2.5 to 2.8 g, using PVC/PE foil as primary packaging

→ 550 Tons - Yearly production capacity

- energetic efficiency- System BMS/EMS (Building Management System/Environment Monitoring System)
- flexibility in operation
- optimization of energy consumption
- state-of-the-art-technology
- real-time proces control
- product quality safety
- multiple monitoring parameters

→ Worldwide presence through our partnerships, conducting successful audits and cooperations with International Authorities.

→ Product development in our Research & Development Center with the possibility to manufacture in our new state-of-the-art facility.



D - Dermatologicals

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
D01 – Antifungals for dermatological use							
1	clotrimazole	Clotrimazol ATB® 10 mg/g	cream	Canesten, Bayer	OTC	Box x 1 tube x 20 g Box x 1 tube x 30 g	EU eCTD Q4 2023
D07 – Corticosteroids, dermatological preparations							
1	betamethasone dipropionate	EKARZIN® 0.5 mg/g	cream		Rx	Box x 1 tube x 15 g	*
2	betamethasone dipropionate + salicylic acid	SAL-EKARZIN® 0.50 mg/30 mg/g	ointment		Rx	Box x 1 tube x 15 g	*
3	clotrimazole + betamethasone dipropionate	CLO-EKARZIN® 0.50 mg/10 mg/g	cream		Rx	Box x 1 tube x 15 g	*
4	clobetasol propionate	Clobetasol ATB® 0.50 mg/g	cream		Rx	Box x 1 tube x 25 g	**
5	clobetasol propionate	Clobetasol ATB® 0.50 mg/g	ointment		Rx	Box x 1 tube x 25 g	EU eCTD Q3 2024
6	fluocinolone acetonide + neomycin sulfate	Fluocinolone N ATB® 0.25 mg/5 mg/g	ointment		Rx	Box x 1 tube x 18 g	*
7	mometasone furoate	Mometasone ATB® 1 mg/g	cream		Rx	Box x 1 tube x 15 g	**
8	mometasone furoate	Mometasone ATB® 1 mg/g	ointment		Rx	Box x 1 tube x 15 g	**
9	nystatin + neomycin sulfate + triamcinolone acetonide	NIDOFLOR®	cream		Rx	Box x 1 tube x 15 g	*

* Dossier with limited production and/or regulatory support

** Dossier availability depending on country legislation

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M – Musculo-skeletal system

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
M01A – Antiinflammatory and antirheumatic products, non-steroids							
1	paracetamol + diclofenac sodium	ACECLOFEN®	suppositories		Rx	Box x 6 suppositories Box x 12 suppositories	**
2	diclofenac sodium	CLAFEN® 100 mg	suppositories		Rx	Box x 6 suppositories Box x 12 suppositories	**
M02 – Topical products for joint and muscular pain							
1	diclofenac diethylamine	CLAFEN® RAPID 11.6 mg/g	gel	Voltaren, GSK	OTC	Box x 1 tube x 40 g	EU eCTD Q1 2024
2	diclofenac sodium	CLAFEN® 10 mg/g	gel		OTC	Box x 1 tube x 40 g Box x 1 tube x 100 g	**
3	diclofenac sodium	CLAFEN® FORTE 50 mg/g	gel		OTC	Box x 1 tube x 25 g Box x 1 tube x 45 g Box x 1 tube x 100 g	**

G - Genito-urinary system and sex hormones

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
G01 – Gynecological antiinfectives and antiseptics							
1	metronidazole + clotrimazole	ZIFEX® DUO	pessaries		Rx	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application
2	nystatin	Nystatin ATB® 100 000 IU	pessaries		Rx	Box x 7 pessaries Box x 14 pessaries	EU eCTD Bibliographical Application
3	nystatin + neomycin sulfate + metronidazole + hydrocortisone acetate	ZIFEX® COMPLEX	pessaries		Rx	Box x 7 pessaries Box x 14 pessaries	* Bibliographical Application

** Dossier availability depending on country legislation

C – Cardiovascular System

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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C07- Beta Blocking Agents

1	bisoprolol fumarate	BISOTENS® 5 mg	film coated tablets	Concor, Merck	Rx	Box x 30 tablets	EU eCTD
2	bisoprolol fumarate	BISOTENS® 10 mg	film coated tablets	Concor, Merck	Rx	Box x 30 tablets	EU eCTD
3	carvedilol	GLADYCOR® 6.25 mg	tablets	Dilatrend, Roche	Rx	Box x 30 tablets	EU eCTD
4	carvedilol	GLADYCOR® 12.5 mg	tablets	Dilatrend, Roche	Rx	Box x 30 tablets	EU eCTD
5	carvedilol	GLADYCOR® 25mg	tablets	Dilatrend, Roche	Rx	Box x 30 tablets	EU eCTD
6	nebivolol hydrochloride	NOLET® 5 mg	tablets	Nebilet, Berlin Chemie	Rx	Box x 30 tablets	EU eCTD

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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C08 – Calcium channel blockers

1	amlodipine besilate	ALMACOR® 5 mg	tablets	Norvasc, Pfizer	Rx	Box x 30 tablets	**
2	amlodipine besilate	ALMACOR® 10 mg	tablets	Norvasc, Pfizer	Rx	Box x 30 tablets	**

C09 – Agents acting on the Renin-Angiotensin System

1	candesartan cilexetil	Candesartan ATB® 8 mg	tablets	Atacand, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
2	candesartan cilexetil	Candesartan ATB® 16 mg	tablets	Atacand, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
3	lisinopril dihydrate	Lisinopril ATB® 10 mg	tablets	Zestril, Astra Zeneca	Rx	Box x 20 tablets Box x 30 tablets	EU eCTD
4	lisinopril dihydrate	Lisinopril ATB® 20 mg	tablets	Zestril, Astra Zeneca	Rx	Box x 10 tablets Box x 30 tablets	EU eCTD
5	lisinopril dihydrate	Lisinopril ATB® 40 mg	tablets	Zestril, Astra Zeneca	Rx	Box x 10 tablets Box x 30 tablets	EU eCTD
6	ramipril	Ramipril ATB® 2.5 mg	tablets	Tritace, Sanofi	Rx	Box x 30 tablets	EU eCTD
7	ramipril	Ramipril ATB® 5 mg	tablets	Tritace, Sanofi	Rx	Box x 30 tablets Box x 60 tablets Box x 90 tablets	EU eCTD
8	ramipril	Ramipril ATB® 10 mg	tablets	Tritace, Sanofi	Rx	Box x 30 tablets Box x 60 tablets Box x 90 tablets	EU eCTD

C10 – Lipid modifying agents

1	rosuvastatin calcium	Rosuvastatin ATB® 5 mg	film coated tablets	Crestor, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
2	rosuvastatin calcium	Rosuvastatin ATB® 10 mg	film coated tablets	Crestor, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
3	rosuvastatin calcium	Rosuvastatin ATB® 20 mg	film coated tablets	Crestor, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD
4	rosuvastatin calcium	Rosuvastatin ATB® 40 mg	film coated tablets	Crestor, Astra Zeneca	Rx	Box x 30 tablets	EU eCTD

** Dossier availability depending on country legislation

B – Blood and blood forming organs

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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B01 – Antithrombotic agents

1	acetylsalicylic acid	ROMPIRIN® 100 mg	gastro-resistant film coated tablets	Aspirin Cardio, Bayer	OTC	Box x 20 tablets Box x 50 tablets Box x 1500 tablets	EU CTD
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A – Alimentary tract and metabolism

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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A02 – Drugs for acid related disorders

1	omeprazole	Omeprazol ATB® 20 mg	gastro-resistant capsules		Rx	Box x 20 capsules	EU eCTD
2	omeprazole	NOVOGAST® 20 mg	gastro-resistant capsules		OTC	Box x 10 capsules	EU eCTD

A06 – Drugs for constipation

1	glycerol	Glycerol suppositories for adults	suppositories		OTC	Box x 6 suppositories Box x 12 suppositories	**
2	glycerol	Glycerol suppositories for children	suppositories		OTC	Box x 6 suppositories Box x 12 suppositories	**

A07 – Antidiarrheals, intestinal antiinflammatory / antiinfective agents

1	nystatin	Nystatin ATB® 500 000 IU	film coated tablets		Rx	Box x 20 tablets Box x 1500 tablets	EU eCTD Bibliographical Application
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N – Nervous system

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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N02 – Analgesics

1	paracetamol	Paracetamol ATB® 125 mg	suppositories		OTC	Box x 6 suppositories Box x 12 suppositories	**
2	paracetamol	Paracetamol ATB® 250 mg	suppositories		OTC	Box x 6 suppositories Box x 12 suppositories	**

N07- Other nervous system drugs

1	betahistine dihydrochloride	Betahistine ATB® 8 mg	tablets	Betaserc, Abbot	Rx	Box x 30 tabletsE	U eCTD
2	betahistine dihydrochloride	Betahistine ATB® 24 mg	tablets	Betaserc, Abbot	Rx	Box x 30 tabletsE	U eCTD

V03AB – Antidotes

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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1	potassium iodide	Potassium iodine® 65 mg	tablets		Rx	Box x 30 tablets	**
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** Dossier availability depending on country legislation

Cosmetic products (according to EU legislation)

No	Active substance	Brand name	Pharmaceutical form	Packaging
1	d-panthenol + urea + tocopherol (vitamin E) + phytoceramides + Avena Sativa Kernel Oil	CUTADEN® Repair	cream	Box x 1 tube x 50 ml
2	niacinamide + dexpanthenol(nicotinamide)	TINERO®	gel	Box x 1 tube x 40 g Box x 1 tube x 15 g
3	tea tree oil+ niacinamide (nicotinamide) + lactic acid +salicylic acid + kaolin + Chamomilla Recutita Flower Extract	TINERO® TT Pure	purifying mask	Box x 1 tube x 50 ml
4	tea tree oil + niacinamide (nicotinamide) + salicylic acid	TINERO® TT Quick	cream	Box x 1 tube x 8 ml
5	tea tree oil + niacinamide (nicotinamide) + d-panthenol + lactic acid + salicylic acid + tocopherol (vitamin E)	TINERO® TT Clean	foaming gel	Box x 1 tube x 50 ml
6	tea tree oil + niacinamide (nicotinamide) + sodium hyaluronate + ceramides + Avena Sativa Kernel Flour, Avena Sativa Kernel Oil + tocopherol (vitamin E)	TINERO® TT Drop	cream, moisturizer	Box x 1 tube x 50 ml
7	troxerutin + d-panthenol	FLUXIV®	cream	Box x 1 tube x 20 g Box x 1 tube x 40 g Box x 1 tube x 100 g
8	panthenol + Jojoba Oil + Sweet Almond Oil + Shea butter + tocopherol (vitamin E) + zinc oxide	CUTADEN® Bebe	cream	Box x 1 tube x 50 ml
9	zinc oxide + ichthammol +hamamelis virgiana extract	CUTADEN®	cream	Box x 1 tube x 35 ml



Nutriensa®

Food supplements- Nutriensa Line (according to Romanian legislation)

N _c	Active substance	Brand name	Pharmaceutical form	Packaging	Therapeutic class
1	ascorbic acid + iron + zinc lactate dihydrate	FEZIVIT C®	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	health of skin, hair, nails
2	bifidobacterium animalis ssp lactis BL-G101 +Bifidobacterium longum ssp longum BL-G301 +Bifidobacterium longum ssp infantis BI-G201 + Lactobacillus acidophilus LA-G80 + Lactobacillus plantarum Lp-G18 +Lactobacillus rhamnosus Lr-G14 +Lactobacillus paracasei LPc-G110 +Lactobacillus reuteri LR-G100 +Inulin +Vitamin D3 (Cholecalciferol)	SIMBIFLORA KIDS	sachets	Box x 10 sachets Box x 20 sachets	microbiome, immunity
3	bifidobacterium bifidum BB-G90 +Bifidobacterium animalis ssp lactis BL-G101 +Bifidobacterium breve BB-G95 lactobacillus acidophilus LA-G80 + lactobacillus plantarum Lp-G18 + lactobacillus rhamnosus Lr-G14 + lactobacillus paracasei LPc-G110 + lactobacillus gasseri LG-G1+FOS (fructo-oligo-zaharide)+ zinc gluconate +vitamin D3 (Cholecalciferol)	SIMBIFLORA FORTE	capsules	Box x 10 capsules Box x 20 capsules	microbiome, immunity
4	bifidobacterium breve BB-G95+ bifidobacterium bifidum BB-G90+ bifidobacterium animalis ssp lactis BL-G101+ bifidobacterium longum ssp longum BL-G301+ bifidobacterium longum ssp infantis BI-G201+ lactobacillus plantarum Lp-G18 +lactobacillus rhamnosus Lr-G14 + lactobacillus delbrueckii ssp bulgaricus LB-G40 +lactobacillus casei LC-G11 +lactobacillus salivarius LS-G60 +lactobacillus helveticus LH-G51 +FOS (fructo-oligo-zaharide) + selenium enriched yeast + vitamin E (dl-α-tocopheryl acetate)	SIMBIFLORA COMPLEX	capsules	Box x 10 capsules Box x 20 capsules	microbiome, immunity
5	D-mannose +cranberry fruit extract (vaccinium macrocarpon) standardized in 25% proanthocyanidins (PAC tip A) + zinc lactate dihydrate	UREXPERT®	film-coated tablets	Box x 10 film-coatedtablets Box x 20 film-coated tablets	genitourinary system health
6	fish oil 1000 mg (600/ 150 EPA/ DHA) + vitamin E acetate (DL- alpha- tocopheryl acetate) + coenzyme Q10 + lycopene oil 6%	TRI OLI®	capsules soft	Box x 4 capsules soft Box x 15 capsules soft Box x 30 capsules soft	heart health
7	guarana seeds extract (paullinia cupana) standardized in at least 22% caffeine + vitamin B3 (Niacine) + L-glutamine +taurine + tryptophan	SORISO® ENERGY	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	central nervous system health
8	polygonum cuspidatum root extract standardized in at least 50% trans-resveratrol+ ginkgo biloba leaves extract standardized in at least 24% ginkgoflavonoids and 6% lactone terpenes + Vitamin B6 (pyridoxine hydrochloride)	SORISO® ACTIV	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	central nervous system health
9	rhodiola or "golden root" extract (rhodiola rosea) standardized in at least 3% rosavine and 1% salidroside + basil extract (ocimum basilicum) standardized in at least 2% ursolic acid	SORISO®	tablets	Box x 10 tablets Box x 30 tablets Box x 60 tablets	central nervous system health
10	magnesi e dihydrate + vitamin B6 (pyridoxine hydrochloride)	EQUILIBRA®	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	supporting metabolism

**Food supplements- Nutriensa Line** (according to Romanian legislation)

No	Active substance	Brand name	Pharmaceutical form	Packaging	Therapeutic class
11	magnesium malate trihydrate + magnesium bisglycinate + vitamin B6 (pyridoxine hydrochloride)	EQUILIBRA® PLUS	film-coated tablets	Box x 10 film-coated tablets Box x 30 film-coated tablets	supporting metabolism
12	organic vitamin C as hibiscus flower extract (hibiscus sabdariffa) standardized in at least 5% vitamin C + echinacea aerial part extract (echinacea purpurea) standardized in at least 4% polyphenols + echinacea root extract (echinacea angustifolia) standardized in at least 4% echinacosides + zinc dihydrate lactate	IMUNOFIX®	film-coated tablet	Box x 10 film-coated tablets Box x 30 film-coated tablets Box x 60 film-coated tablets	supporting immunity system
13	senna leaf extract (Cassia angustifolia) standardized in at least 20% sennosides + rhubarb root extract (rheum palmatum) standardized in at least 5% rhein + ginger root extract (zingiber officinale) standardized in at least 5% gingerols + organic vitamin C as hibiscus flower extract (Hibiscus sabdariffa) standardized in at least 5% vitamin C	LEJER®	capsules	Box x 10 capsules Box x 20 capsules	health of the digestive system
14	silymarin seeds extract (silybum marianum) standardized in at least 80% silymarin + L-methionine + L-cysteine	SILITHOR®	capsules	Box x 10 capsules Box x 30 capsules Box x 60 capsules	liver health
15	troxerutin + diosmine + hesperidine + vitamin C (ascorbic acid)	FLUXIV®	film-coated tablet	Box x 60 tablets	peripheral circulation health
16	yellow tablet chondroitin sulfate sodium + ascorbic acid + zinc lactate dihydrate white tablet glucosamine sulfate potassium chloride + hyaluronic acid (sodium salt)/sodium hyaluronate	SPRINTEN®	film-coated tablets	Box x 20 film-coated tablets (1 blister x 10 yellow film-coated tablets + 1 blister x 10 white film-coated tablets) Box x 60 film-coated tablets (3 blisters x 10 yellow film-coated tablets + 3 blister x 10 white film-coated tablets)	joint health

Pipeline

J - Antiinfectives for systemic use

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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J01 - Antibacterials for systemic use

1	cefixime	EFICEF® 400 mg	capsules	Unasyn, Pfizer	Rx	Box x 10 capsules	Q4 2023
2	rifaximine	Rifaximine 200 mg	capsules	Normix 200 mg Alfasigma	Rx	Box x 30 capsules	Q2 2024

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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A- Alimentary tract and metabolism

1	famotidine, calcium carbonate, magnesium hydroxide	Famotidine/calcium carbonate/ magnesium hydroxide 10 mg/800 mg/165 mg	tablets		Rx	Box x 10 vials	Bibliographical application Q2 2025
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D - Dermatologicals

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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D06 - Dermatologicals, antibiotics for topical use

1	neomycin sulfate + bacitracin zinc	ZINBA®5000 IU/250 IU/g	ointment	Baneocin, Sandoz	OTC	Box x 1 tube x 20 g	EUeCTD Hybrid application Q3 2024
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G - Genito-urinary system and sex hormones

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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G01 - Gynecological antiinfectives and antiseptics

1	metronidazole, nystatin, neomycin sulfate	ZIFEX® TRIO	pessaries	Tergynan, Lab Bouchara	RX	Box x 10 pessaries	EUeCTD Hybrid application Q4 2024
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M - Musculo-skeletal system

No	Active substance	Brand name	Pharmaceutical form	Reference medicine	Rx/OTC	Packaging	File status
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M01 - Antiinflammatory and antirheumatic products

1	naproxen sodium, esomeprazole magnesium	Naproxen/ Esomeprazol 500 mg/20 mg	modified-release tablets	Vimovo, AstraZeneca	OTC	Box x 10 tablets	EUeCTD Generic application Q4 2024
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N - Nervous System

N01 - Anesthetics, local

1	prilocaine, lidocaine hydrochloride	DUOCALM® 25 mg/25 mg/ g	cream	EMLA, Astra Zeneca	Rx	Box x 1 tube x 5 g Box x 1 tube x 30 g	EUeCTD Hybrid application Q2 2025
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Medical devices (according to Regulation EU 2017/745)

No	Active substance	Brand name	Packaging	File status
1	polysiloxanes, trimethylsiloxysilicate, dimethicone crosopolymer	SILODERM® gel (non-sterile silicone gel for hypertrophic and keloid scars)	box x 1 tube x 15g	DM Class I, available Q3 2023
2	sodium hyaluronate	ZIFELLE® Hydra vaginal pessaries	box x 10 pessaries	DM class IIa, CE mark Q3 2024
3	sodium hyaluronate lactic acid sodium lactate	ZIFELLE® Hydra vaginal moisturizer cream	box x 1 tube x 50g (with applicator)	DM class IIa, CE mark Q3 2024
4	lactic acid sodium lactate	ZIFELLE® vaginal pessaries	box x 10 pessaries	DM class IIa, CE mark Q3 2024
5	sodium hyaluronate DL-A-Tocopheryl acetate menthol	HEMORSAL® antihemorrhoidal suppositories	box x 7 suppositories	DM class IIa, CE mark Q3 2024
6	sodium hyaluronate DL-A-Tocopheryl acetate menthol	HEMORSAL® antihemorrhoidal cream	box x 1 tube x 30g (with applicator)	DM class IIa, CE mark Q3 2024

DISCLAIMER: These products cannot be supplied into countries in which their use and/or commercialization may be in conflict with existing IP rights of a third party. In any event, any use and/or commercialization in breach of the above will be made under your sole and/or the final buyer's responsibility (as the case may be) and you will keep us fully indemnified and harmless from any claims and consequences arising out of such commercialization, use and breach.





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-  tablets, capsules
-  creams, ointments, topical powders
-  pessaries



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- ➔ **This polymorphic form A (dihydrate) is maintained after micronisation, which proves a reproducible process.**
- ➔ **Purity and polymorphic stability ensures a clear advantage in the formulation of finished products, regardless of their pharmaceutical form (tablets, topical products or suspensions).**

NYSTATIN MICRONIZED

Quality according current edition of the EP/ USP Pharmacopeia

- **PARTICLE SIZE** 90% of particles no more than 10 μm
100% of particles no more than 15 μm
- **PACKING** polyethylene bags inserted in triple layer PET/ Al/ PE bags and placed in cardboard boxes
- **STORAGE** store below 25°C in original packaging, protected from light
- **RETEST** 36 months

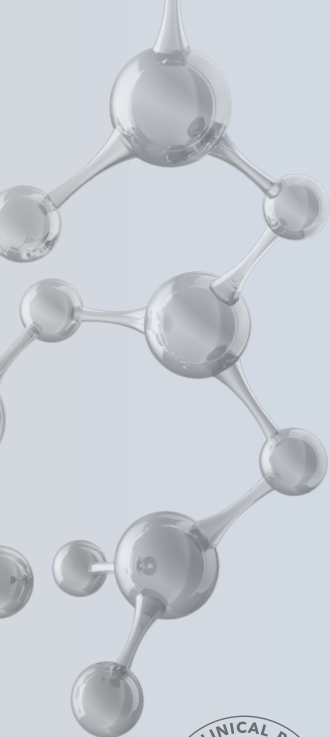
NYSTATIN NON- MICRONIZED

Quality according current edition of the EP/ USP Pharmacopoeia

- **PARTICLE SIZE** 90% of particles no more than 45 μm
- **PACKING** polyethylene bags inserted in triple layer PET/ Al/ PE bags and placed in cardboard boxes
- **STORAGE** store below 25°C in original packaging, protected from light
- **RETEST** 36 months



Fully Integrated Certified Contract Research Organization



20 years of experience
in Developing and
Conducting Clinical Trials



The **Clinical Trials Center** (CTC) is a full service Contract Research Organization (CRO), authorized by National Agency for Medicines and Medical Devices of Romania, which performs phase I clinical trials and bioequivalence (BE) studies.

For more than **20 years**, many generic pharmaceutical companies have registered their products all over the world, using our expertise in conducting clinical studies on Antibiotice's site.

The CTC benefits a fully integrated organizational structure located on one site, consisting of:

- a GCP inspected Clinical Unit
- a GLP certified Analytical Unit - state-of-the-art laboratory equipment and technologies;
- a GMP certified IMP secondary packaging line (for the packaging and labeling of investigational medicinal products).

Complete clinical services from protocol development to dossier application, in compliance with the latest international regulations.

➔ Client-oriented CRO

- We offer facilities and services for conducting Phase I clinical trials and bioequivalence studies for many medicinal products covering a broad of therapeutic areas
- We offer expert advice (scientific, regulatory) taking into account the current regulations for the biopharmaceutics industry and the requirements of regulatory agencies
- We provide innovative and high-quality services, with integrity and reliability
- We provide Quality Guarantee our Internal Quality Assurance and Quality Control Units develop well-designed sets of Standard Operating Procedures (SOPs) and ensure that clinical trials are conducted according to the Harmonized European Legislation (ICH), Integrated Management System (ISO 9001, ISO 14001, ISO 45001), Good Clinical and Laboratory Practice guidelines and Helsinki Declaration

Services offered by Antibiotice's Clinical Trials Center

➔ **Medical writing and Study Management**

- Clinical Project management
- Protocol development
- Informed consent forms, including local language ICFs (prepared and reviewed by the relevant country)
- Clinical trial reports according to ICH E3 and eCTD format
- Regulatory applications and submissions to the EC & regulatory authorities
- Archiving of essential trial documents and all the related data
- Safety reporting and other pharmacovigilance activities related to the clinical studies
- GCP monitoring and auditing

➔ **Bioanalytical services:**

- Development and validation of LC-MS/MS, LC-UV and LC fluorescence bioanalysis
- Quantification of multianalytes metabolites, prodrugs, light and temperature - sensitive compounds in various biological matrixes
- Transfer and revalidation of Sponsor method
- GLP auditing and quality control

➔ **Data Management&Biostatistics**

- CRF design
- Database Design and Validation
- Medical Coding
- Data Entry
- Biostatistics
- PK; PK/PD analysis

➔ **Research and Development**

offers various Analytical Services, Formulation Services and Pharmaceutical Services, such as:

- Reverse engineering of the reference drug product
- Development and validation of in-house analytical methods
- Design of pharmaceutically equivalent drug products, in different pharmaceutical forms:
 - conventional, modified release or gastro-resistant tablets
 - hard gelatin capsules
 - gels, creams, ointments
 - suppositories and pessaries
 - powders for solutions/ suspensions for injection (beta-lactam penicillins in low volumes)
- Monitoring drug product through stability studies
- Design of the manufacturing process
- Pilot technology for research and development

➔ **Regulatory expertise**

- Differentiated regulatory strategies for EU, USA and other countries for drug product and active substances sustained by Regulatory Affairs experts
- Full regulatory support for eCTD, NeeS and paper submission
- Multilingual packaging and labeling
- Maintenance of regulatory approvals throughout their lifecycle

➔ **Pharmacovigilance Services**

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Product portfolio



Integrated Annual Report

