

I represent Georgian Pharmaceutical company “Aversi-Rational”. It is the largest world level manufacturer of pharmaceuticals not only in Georgia, but in the whole Transcaucasia. It produces efficient, reliable and safe products of the highest quality on the pharmaceutical market; creates stable jobs and expands production. The first “Aversi-Rational” medicine was presented in March 2005; Nowadays there are produced medicines of 153 names; 239 positions;

The company exports its products to: Kirgizstan, Armenia, Azerbaijan, Ukraine, Iraq and other countries of the Near East and South; The certificates owned by “Aversi-Rational” prove the fact that it is the world-class manufacturer. There are annually carried out verification procedures and once in three years – a re-certification, which is implemented by two leading German companies (TÜV SÜD and TÜV Cleancert); “Aversi-Rational” has managed to acquire international certificates in a very short period of time. The certificate ISO 9001 was received in 2006; Since 2008 “Aversi-Rational” has become the owner of the European GMP EU and US FDA GMP certificates of compliance that prove the fact that all the processes implemented at “Aversi-Rational” (production, quality control, quality assurance and etc.) correspond to the requirements of the European and US standards; As physico-chemical, as microbiological analyses are carried out at the modern “Aversi-Rational” laboratory. It occupies 750 sq. meters of the factory's territory. Since January 2014, the fact of having been accredited in compliance with the standard ISO/IEC 17025, proves the technical competence of the laboratory; The laboratory of “Aversi-Rational” corresponds to all standards required from the world leading pharmaceutical manufacturers. The new laboratory, as the whole factory, is equipped only with the latest European, American and Japanese machinery and inventory that in turn is the guarantee of reliability of all implemented analyses; The raw materials are purchased only from the world famous pharmaceutical companies; the quality and safety of the raw materials is afterwards checked at the laboratory; All machinery applied during the manufacturing processes is provided by the best European, US and Japanese manufacturers in the whole world. There is regularly held machinery qualification procedure that provides a documented confirmation of the fact that the work of the machinery is efficient and stable; The personnel of “Aversi-Rational” regularly attends particular trainings on the rules of the work on the modern machinery as in Georgia, as well as abroad, mainly at the manufacturing complexes of the producers; The demand for the “Aversi-Rational” products has significantly risen not only on Georgian, but on the foreign market as well, that in turn proves the fact that the products are reliable and of high quality.

African markets are very attractive and perspective for us, we are glad that we have the chance to cooperation with you, I hope It will contribute to not only success of Aversi-Rational in Africa, but it will be the basis of our countries friendship. our goal is to sell medicine produced by Aversi Rational in the territory of Africa, to start business in your country we need your support in following items.

1. To submit registration requirement for pharmaceutical product
2. To ensure registration of medicine.
3. to submit Pharma market date

4. To contact with leader distributor company of pharmaceutical product.
5. To participate in government purchase

we will submit registration dossier according to requirement and we will create a demand of our products.

Hope on you support and kind understanding



N	Trade Name	INN Name	Pharmacological Group
Cardiovascular system			
1	Raunatin 2mg tab. №10	Rauwolfia alkaloids	Antyhypertensive
2	Anaprilin 10mg tab. №50	Propranolol	Nonselective beta-blockers
3	Anaprilin 40mg tab. №50		
4	Ratenal 25, tab. №50	Atenolol	Selective beta-adrenoblocker
5	Ratenal 50, tab. №50		
6	Ratenal 100, tab. №50		
7	Avecor 2.5-Aversi tab. №30	Bisoprolol	Selective beta-adrenoblocker
8	Avecor 5-Aversi tab. №30		
9	Avecor 10-Aversi tab. №30		
10	Nonblon 5mg, tab. №20	Nebivolol	Third-generation Beta-adrenoblocker with vasodilating propertis,
11	Nonblon H tab. №20	Nebivolol, hydrochlorothiazide	Antihypertensive agent
12	Cardirat 6.25 mg, tab. №30	Carvedilol	Alpha and beta blocking agents
13	Cardirat 12.5 mg, tab. №30		
14	Cardirat 25 mg, tab. №30		
15	Capt 12.5 mg, tab. №50	Captopril	Antihypertensive agent;
16	Capt 25 mg, tab. №50		
17	Enozid H tab. N20	Enalapril, hydrochlorothiazide	Combined anti-hypertensive agent
18	Enozid HL tab. N20		
19	Quadrica 10 tab. №30	Lisonopril	Antihypertensive
20	Quadrica 20 tab. №30		
21	Quadrica H mite tab. №30	Lisonopril and hydrochlorothiazide	Combined antihypertensive agent
22	Quardica H tab. №30		
23	Quadrica H forte tab. №30		
24	Quadripin tab. №30	Lisonopril and Amlodopin	
25	Amtas-Aversi 5mg tab. №20	Amlodipine	Slow calcium-channel blocker
26	Amtas-Aversi 10mg tab. №20		
27	Cardio force 75mg, tab. №30	Acetylsalicylic acid	Platelet aggregation inhibitors excl. heparin
28	Cardio force 150 mg, tab. №30		
29	Clopidon 75 mg, tab. №10	Clopidogrel	Platelet aggregation inhibitor
30	Staticor-Aversi 10mg, tab. №30	Simvastatin	
31	Staticor-Aversi 20mg, tab. №30		
32	Ratizol Plus 10/10 mg tab №30	Atorvastatin / Ezetimibe	Hypolipidemic agent

33	Ratizol 10 10 mg tab №30	Atorvastatin	
34	Ratizol 20 10 mg tab №30		
35	Ratizol 40 10 mg tab №30		
36	Mildroxyn 250 mg caps.№40	Meldonium	Other cardiac preparations
37	Mildroxyn 10% 5 ml №10 ampoules		
38	Dilox 2 ml №5 amp.	Ethyl-methyl-hydroxypyridine succinate	Antioxidant
39	Tard N5 ampoules	Norepinephrin (noradrenalin hydrotartrate)	Adrenergic and dopaminergic agents
40	Leron tab. №50	Furosemide, amyloside	Combined diuretic agent

Drugs for gastrointestinal disorders

41	Anber tab. №10	Dicycloverine, Paracetamol	Spasmolytic, antipyretic and analgesic agent
42	Pesto tab. №100	Hyoscine butylbromide	Spasmolytic and cholino-blocker agent
43	Pesto №10 ampoules		
44	Bauzole tab. №10	Rabeprazole	Preparation for the treatment of ulcer and gastroesophageal reflux
45	Lan-30-Aversi caps. №30	Lansoprasol	Proton pump inhibitor
46	Omezol caps. №20	Omeprazole	Proton pump inhibitor
47	Omeprazole caps. №50		
48	Ulceron №14 combined kit	Lansoprasol; Tinidasol; Clarythromicine	Combination for eradication of Helicobacter pylori
49	Entenorm capsules №20	Combined preparation	Eubiotics, agent regulating bowel micro flora
50	Enzal D capsules №30	Combined preparation	Enzyme agent
51	Colin 40mg, caps. №30	Simeticone	Anti-flatulent
52	Colin 40mg/ml 30ml susp. №1 vial		
53	Mold 10 mg tab №20	Racecadotril	Antidiarrheal agent
54	Mold 100mg caps №30	Racecadotril	Antidiarrheal agent
55	Brulium linguatabs tab. №20	Domperidone	Peristaltic stimulant
56	Picolax 0.75% 15 ml dpros	Sodium picosulfate	laxative
57	Picolax 10mg № 30 tab	Sodium picosulfate	laxative
58	Choleron 300 mg, caps. №20	Ursodeoxycholic acid	Hepatoprotector with choleric and cholelithic action
59	Ludox 355/120 mg, tab. №20	Hydrolyzed lignin/Lactulose	Enterosorbent

60	Hepolam, caps. № 30	Combined preparation	Hepatoprotector
61	Hepolam, 100ml Syrup №1 vial		

Antinflammatory and antirheumatic agents, NSAID

62	Dicloferol 50 mg, tab. №20	Potassium diclofenac	Anti-inflammatory, analgesic, non-steroidal agent
63	Dicloferol N, №5 ampoules	Sodium diclofenac	
64	Diclofenac-Aversi, №5 ampoules		
65	Ketamo 10 mg tab. №100	Ketorolac	Anti-inflammatory and antirheumatic, non-steroid. Acetic acid derivatives.
66	Ketamo 30mg/1ml №10 amp.		
67	Keto-gel 2.5% 30g №1 tube	Ketoprofen	Anti-inflammatory, non-steroidal agent for topical use
68	Magenol tab. №30	Nimesulide	Anti-inflammatory, analgesic, non-steroidal agent
69	Mobicam 7.5 mg №20	Meloxicam	Non-steroidal, antirheumatic and anti-inflammatory agent
70	Mobicam 15 mg №20		
71	Pacol 500 mg tab. №50	Paracetamol	Analgesic, antipyretic
72	Bebit 100mg/5ml susp. №1 vial	Ibuprofen	Anti-inflammatory, analgesic, antipyretic, non-steroidal agent
73	Perin caps. №50	Acetylsalicylic acid, Paracetamol, Caffeine	Acetylsalicylic acid in combination

Nervous System

74	Blestar 8 mg tab. №30	Betahistine	Antivertigo agent
75	Blestar forte 16 mg tab. №30		
76	Blestar 24 tab. №20		
77	Optimal tab. №10	Zopiclone	Hypnotic agent
78	Corsiz tab. №100	Ethyl ether of alpha-bromisovalerian acid; fenobarbital; mentha oil	Sedative agent
79	Neiromidin-Aversi 20mg, tab. №50	Ipidacrine	Cholinesterase inhibitor, stimulator of neuromuscular conduction
80	Neiromidin-Aversi 1.5% amp. №10		
81	Neiromidin-Aversi 0.5% №10 ampoules		
82	Adaptol-Aversi 300mg, tab. №20	2.4.6.8-Tetramethyl-2.4.6.8-Tetraazabicyclo (3.3.0) Octandion-3.7; (Mebicar)	Anxiolytic agent (tranquilizer)

83	Adaptol-Aversi 500mg, tab. №20	2.4.6.8-Tetramethyl-2.4.6.8-Tetraazabicyclo (3.3.0) Octandion-3.7; (Mebicar)	Anxiolytic agent (tranquilizer)
84	Noofen-Aversi tab. №20	Phenibut (Gamma-amino-beta-phenylbutirate hydrochloride)	Nootropic agent
85	Viner caps. №30	Piracetam, Gamma-aminobutyric acid	Combined nootropic agent
86	Glatan 30 mg #20 tab	Vincamine	Nootropic agent
87	Memortab N caps. №30	Bacopa monnieri, Convolvulus pluricaulis, Withania Somnifera, Nardostachys jatamansi	Combined herbal agent for memory improvement
88	Memortab 100 ml syrup №1 vial	Bacopa monnieri, Convolvulus pluricaulis, Centella Asiatics	
89	Convurat 200 mg tab. №50	Carbamazepine	Antiepileptic
90	Calm №30 caps	Combined herbal agent	Sedative and Hypnotic
91	Sedalon 0.25 g tab. №30	Alprazolam	Anxiolytics. Benzodiazepine derivatives.
92	Sedalon 0.5 g tab. №30		
93	Sedalon 1 g tab. №30		

Antibacterial Agent			
94	Avezol-Aversi vial №1	Cefazolin	First-generation Cephalosporins
95	Sperex 250 mg, caps. №10	Cefaclor	Second-generation cephalosporins
96	Sperex 500 mg, caps. №10		
97	Sperex 125 mg/5 ml Powder for oral suspension		
98	Ratiocef-Aversi 0.5g №1 vial	Ceftriaxone	Third-generation cephalosporins
99	Ratiocef-Aversi 1g №1 vial	Ceftriaxone	Third-generation Cephalosporins
100	Avexon-Aversi 1g vial №1		
101	Avexon-Aversi 2g vial №1		
102	Kvadimax 100mg, tab. №10	Cefpodoxime	Third-generation Cephalosporins
103	Kvadmax 200mg, tab.№10		
104	Kvadimax (suspension) №1 vial		
105	Dardum 1g №1 vial	Cefoperazone	Third-generation cephalosporins
106	Dardumbact 1g №1 vial	Cefoperazone/Sulbactam	Third-generation Cephalosporins
107	Dardumbact 2g №1 vial	Cefoperazone/Sulbactam	Third-generation Cephalosporins
108	Primacef, №1 vial	Cefepim hydrochloride	Fourth-generation cephalosporins
109	Arsogil 250 mg caps. №50	Amoxicillin	Penicillins with extended spectrum
110	Arsogil 500 mg caps. №50		

111	ampiox 0.25g #50 caps	Ampicilin+Oxacilin	Semi-synthetic penicillins.
112	Steptenbact 4.5g №1 vial	Piperacillin / Tazobactam	Combined Antibacterial Agent
113	Sinogal 750mg №1 vial	Ampicillin / Sulbactam	Antibacterial Agent (Penicillin+Beta-lactam antibiotic)
114	Sinogal 1.5mg №1 vial		
115	Likacin 500 mg/2ml №10 vial	Amikacine	Antibiotic of aminoglycoside group
116	Topt 250mg caps. №10	Azithromycin	Macrolides
117	Topt 500mg tab. №10		
118	Topt 200mg/5ml 15ml № 1vial.		
119	Roxitas-Averssi 150mg, tab. №10	Roxithromicine	Antibiotic of macrolide group
120	Roxitas-Averssi suspension, №1 vial		
121	Ceflox-Averssi 500mg, tab. №50	Ciprofloxacin	Anti-bacterial agent of fluoroquinolones
122	Oflotas-Averssi 200mg, tab. №10	Ofloxacin	Antibiotic of fluoroquinolones group
123	Dominal tab. №10	Moxifloxacin	Antibacterial agent of Fluoroquinolones
124	valmox 500	Levofloxacin	Anti-bacterial agent of fluoroquinolones
125	Garde-Rational 1g, №1 vial	Meropenem	Carbapenems

OTHER ANTIBACTERIALS

126	Furamag – Averssi 50 mg, caps. №30	Furaginum	Antibacterial agent, nitrofurane derivatives
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Antiviral agent and immunostimulant

127	Mitanga 500 mg tab. №10	Valaciclovir	Antiviral agent
128	Lemudor 50 mg, tab. №10	Arbidol	Antiviral Agent
129	Lemudor 100 mg, tab. №10		
130	Avurin caps. №30	Combined herbal agent	Herbal Immunostimulant
131	Avurin syrup 100ml №1 vial		

Antifungal , Antihelminthic, Antiprotozoal agent

132	FCN-50 capsule №7	Fluconazole	Antifungal agent for systemic use
133	FCN-150 capsule №1		
134	Musitrol tab. №14	Terbinafine	Antifungal agent
135	Musitrol (crème) №1tube		

136	Itaspor-Aversi 100mg, caps. №10	Itraconazol	Antifungal agent for systemic use, produced by triazole
137	Cipzol 20g, cream in tube №1	Clotrimazol	Antifungal agent
138	Vikazid tab. №10	Mebendasole, Pirantel	Combined Antihelminthic agent
139	Meberix 100 mg tab #10	Mebendasole,	Antihelminthic agent
140	Meberix 100 mg/5ml 30 ml susp #1 vial		
141	Alponal 200mg tab. №10	Albendazole	Antihelminthic agent
142	Secnil 500ml, tab. №6	Secnidazol	Antiprotozoal agent
143	Secnil 1000mg, tab. №6		
144	Metrysol 500 mg tab. №20	Metronidazole	Antiprotozoal agent

Antiseptic for topical use

145	Salbesan №1 tube	Silver sulphadiazine, chlorhexidine gluconate	Anti-microbial agent
146	Liv-angin №16 (Honey&lemon, Strawberry. Orange flavour)	Dichlorobenzyl Alcohol/Amylmetacresol	Antiseptic agent
147	Liv-angin spray №1 vial	Benzidamine / Benzalconium chloride	
148	Baume 5 ml ear drops	Chloramphenicol/clotrimazol/beclometazon/lidocaine	Anti-microbial agent

Mucolytic , expectorant and Anti-cough agent

149	Lizly tab. №50	Ambroxol	Mucolytic and expectorant agent
150	Lizly SR caps. №50		
151	Lizly (syrup) №1 vial		
152	Melon tab. №30	Ambroxole, Salbutamol, Guaifenesin	Broncholytic, mucolytic and expectorant
153	Melon syrup 100ml №1 vial		
154	Muggituse syrup №1 vial	Dextromethorphan, Chlorphenamine	Anti-cough and anti-allergic agent
155	Muggituse tab №20		

Anti cold

156	Ephact C efferv. tab. №10	Acetylsalicylic acid, Ascorbic acid. Caffeine	Anti-inflammatory, analgesic, antipyretic agent
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157	Ephact flu caps. №10	Paracetamol, phenylephrine hydrochloride, chlorpheniramine maleate	Analgesic and antipyretic agent
158	Ephact Tea sachets №10	Paracetamol, phenylephrin hydrochloride, chlorphenamine maleate, ascorbic acid	Analgesic and antipyretic agent
159	Didrop-Aversi 0.05% 10ml nasal drops, №1 vial	Xylometazoline	Nasal drops (Alpha-adrenomimetic agent)
160	Didrop-Aversi 0.1% 10ml nasal drops, №1 vial		
161	Didrop-Aversi 0.05% 15ml nasal spray, №1 vial		
162	Didrop-Aversi 0.1% 15 ml nasal spray, №1 vial		

Antihistamine agent

162	Fenkarol 10 mg, tab. №20	Quifenadine hydrochloride	Antihistamine agent
163	Fenkarol 25 mg, tab. №20		
164	Allerfast 120-Aversi tab. №10	Fexofenadine	Antihistaminic agent
165	Allerfast 180-Aversi tab. №10		
166	Cetek 10 mg, tab. №20	Cetirizine	Antihistamine agent
167	Montof 1mg tab. №50	Ketotifen	Antihistamines

Hypoglycemic agent

168	Sioral retard 500mg tab. №20	Metformin	Peroral hypoglycemic agent
169	Sioral retard 850 mg tab. №20		

Gynecology

170	Ginilac caps. №5	Combined preparation	Agent for regulating of vaginal microflora
171	Relantan 100 mg caps. №30	Progesterone	Gestagens
172	Relantan 200 mg caps. №30		

Urology

173	Salover 0.4 mg caps. №30	Tamsulozine	Selective beta-adrenoblocker
174	Serpens uno caps. №30	Serenoa repens	For the treatment of prostate adenoma
175	Filligra 50 mg, tab №1	Sildenafil	Drug used in erectile dysfunction
176	Filligra 100 mg, tab №1		

Complex of vitamins and minerals

177	Magitron tab. №50	Magnesium, Vitamin B ₆	Combined preparation
178	Magitron effervesc. tab. №20		
179	Centrovit tab. №30	Vitamins and minerals	Complex of vitamins and minerals
180	Lompasar tab. №30	Folic acid	Vitamin
181	Ferrovit caps. №30	Combined preparation with Carbonyl iron	Combined antianemic agent
182	Ferrovit forte caps. №30	Combined preparation with Fumarate iron	
183	Vitaprim C 1g effervesc. tab. №20	Ascorbic acid	Vitamin

Rehydration agent

184	Aysole 4.16 g sachets №20	Sodium chloride; potassium chloride; sodium citrate; anhydrous glucose	Rehydration agent
185	Aysole 20.82 g sachets №20		

Anesthetic agent

186	Tornam №5 ampoules	Bupivacaine	Local Anesthetic agent
187	Somnopol 1%-20ml №5 ampoules	Propofol	General anesthetic agent
188	Somnopol 1%-50ml №1 vial		

Venotonic

189	Flebill caps. №30	Combined agent	Venotonic
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Other drugs for disorders of the musculo-skeletal system

174	Nermo №30 caps	Glucosamin /Vit C/Vit E	Other drugs for disorders of the musculo-skeletal system
175	Nermo Pluse №30 caps	Glucosamin /Chondroitine/Vit C/Vit E/Mn sulf.	

Aversi-Rational Ltd.

Pharmaceutical Manufacture

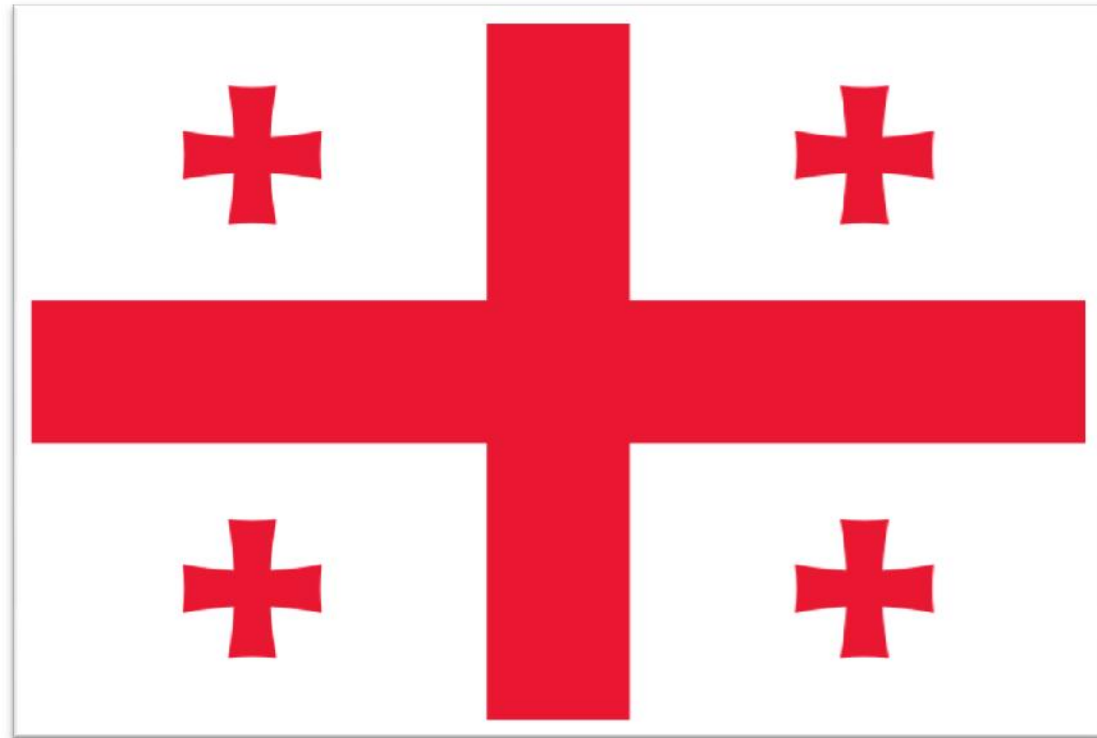




AVERSI - RATIONAL



Welcome!



History of the AVERSI Group



1994: First Drugstore - AVERSI-GEOPHARM

1994: Distribution - AVERSI-PHARMA

2002: Manufacturing - AVERSI-RATIONAL

2007: Medical Service - AVERSI-CLINIC

2009: Health Insurance - ALPHA

AVERSI-RATIONAL in General



Total Area:	≈ 4500 m²
Employees :	≈ 300
Main activity :	Manufacture of pharmaceutical products (Packaging of Bulk Product)
Certified :	ISO 9001 (since 2006) GMP EU (since 2008)



AVERSI-RATIONAL in General



Manufacturing License

ISO 9001:2008



GMP EU & cFDA GMP

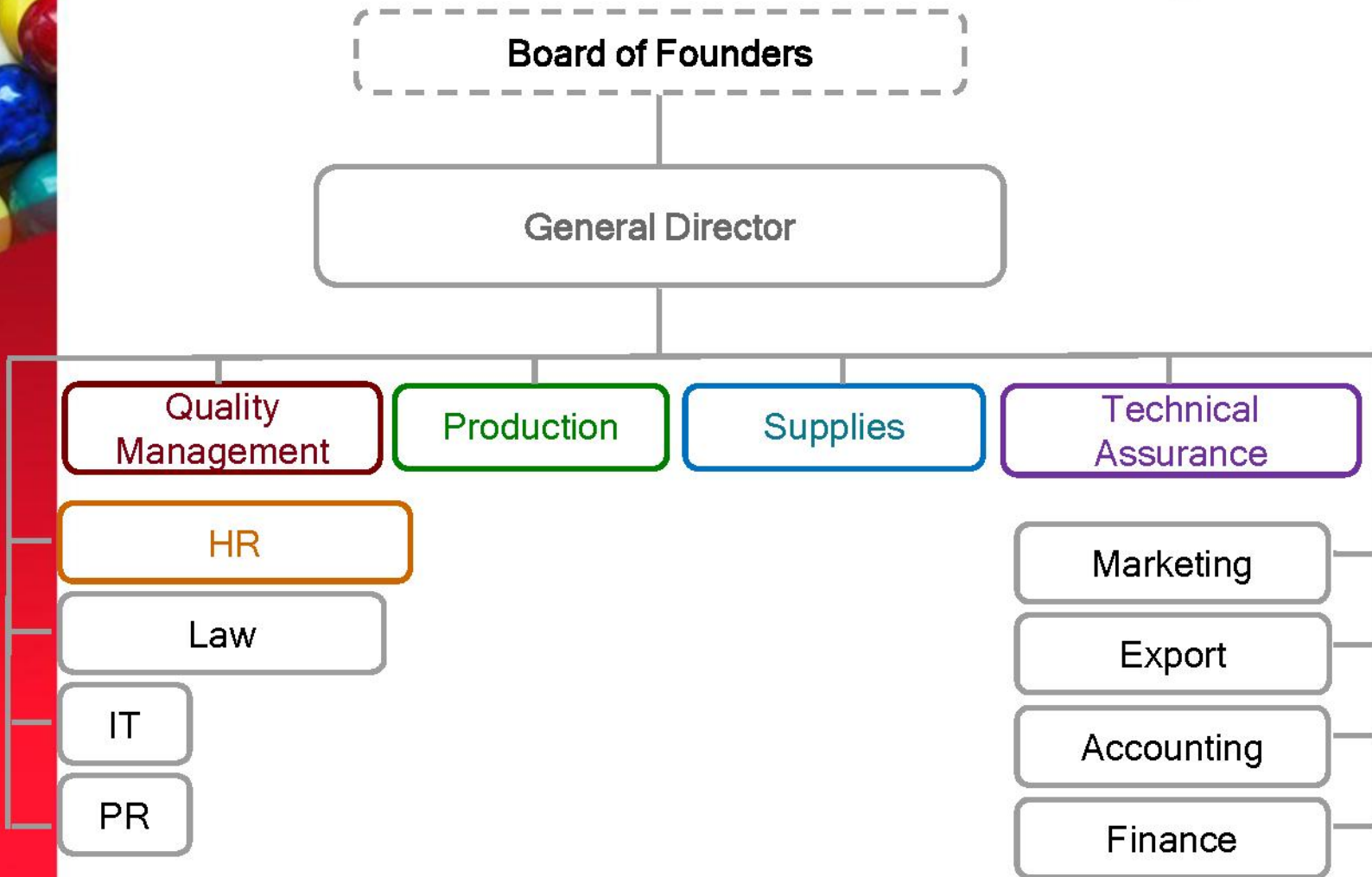


AVERSI-RATIONAL in General



- **ISO and GMP EU & cFDA GMP audits are carried out by the German company TÜV SÜD („TÜV SÜD Management Service“ and „TÜV SÜD Cleancert“)**
- **Control audits are carried out every year**
- **Repeated audits are carried out once In 3 years**

Organizational Structure





Key Staff (Top Management)



Founder
Mr. Kurtanidze Paata
Doctor
Experience – 23 y



Founder
Mr. Kurtanidze Nikoloz
Engineer
Experience – 47 y



Founder/General Director
Mr. Kurtanidze Malkhaz
Pharmacist
Experience – 20 y



Quality Director
Ms. Karukhnishvili Natela
Engineer-Chemist-Technologist,
PhD
Experience – 31 y



Production/Supplies Director
Mr. Ilashvili Bezhan
Chemist
Experience – 12 y



Chief Engineer
Mr. Gurgeniidze Archil
Engineer
Experience – 44 y

Core Values:



Vision: To be the **BEST MODEL** of personally and organizational success all over the world, that will stand for centuries!
To be the **LEADER** among the Leaders!

Mission: Continually assurance the people with pharmaceutical product of high **QUALITY, SAFETY & EFFICIENCY**

Core Values:



Strategy and Quality Policy

- **Following all legislative standards of Georgia and our partner countries, also International standards - ISO 9001, GMP EU & cGMP FDA and providing the full compliance of our processes and product with them**
- **Fulfillment all the wishes and expectations of our customers**
- **Providing safe work places, continual education and stable social environment for our staff**
- **To be the reliable and right partner to all of our customers**



Our Products



- **140 Brand Products, 230 items**
- **Different pharmaceutical groups**



Tablets
Capsules
Dragees
Syrups
Emulsions
Suspensions
Drops
Creams
Gels
Sprays



Solutions for Injection
Powders for Injection



Export Countries:



For the present:

- **Armenia**
- **Kirghizia**
- **Ukraine**

For the future:

- **Uzbekistan**
- **Tajikistan**
- **Kazakhstan**
- **Azerbaijan**
- **Iraq**
- **Kurdistan**
- **Libya**





Our Partners & Suppliers:



Production & Warehouse



Area : $\approx 1800 \text{ m}^2$

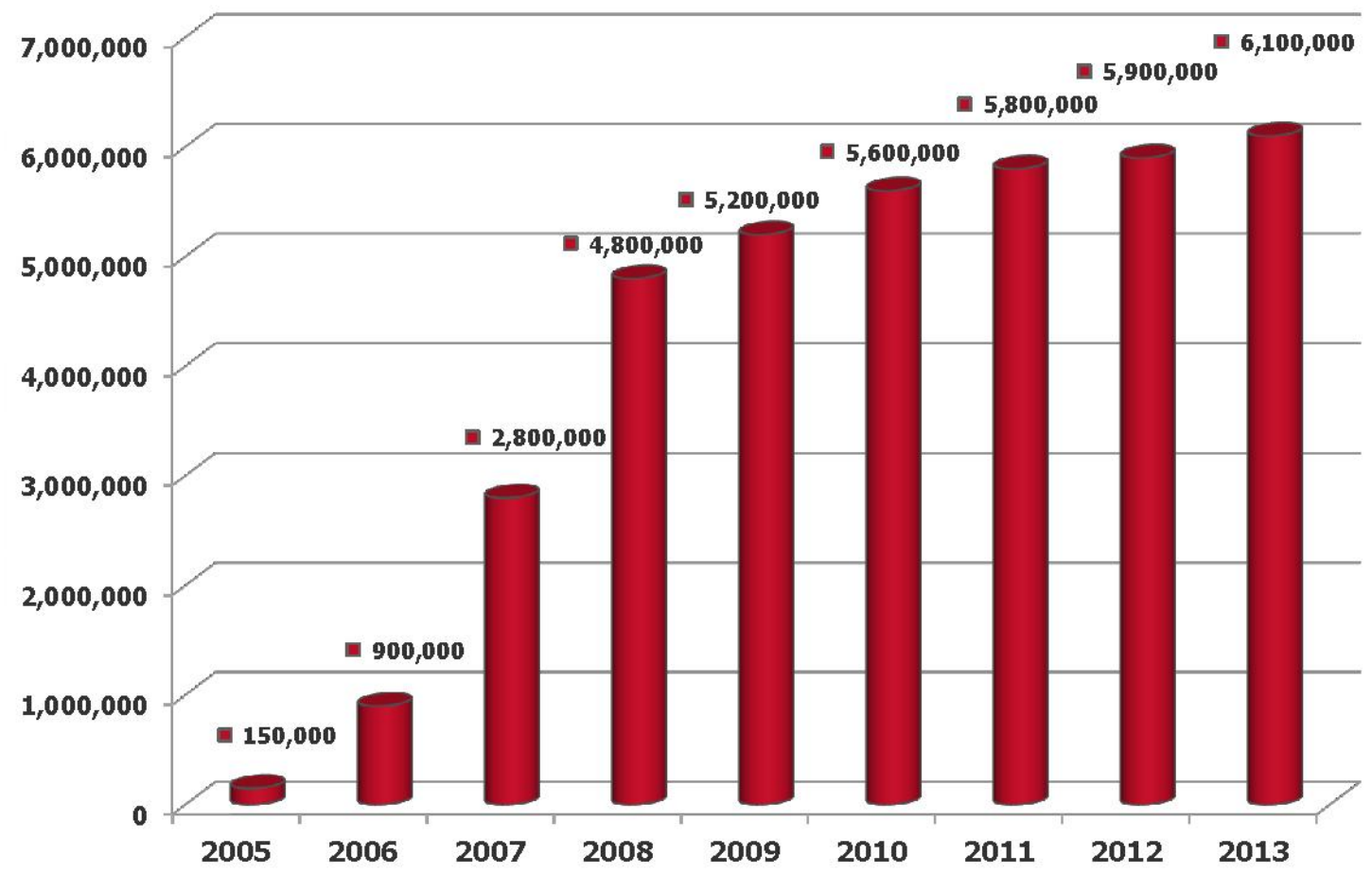
Employees: ≈ 65

First Product: **May 2005**





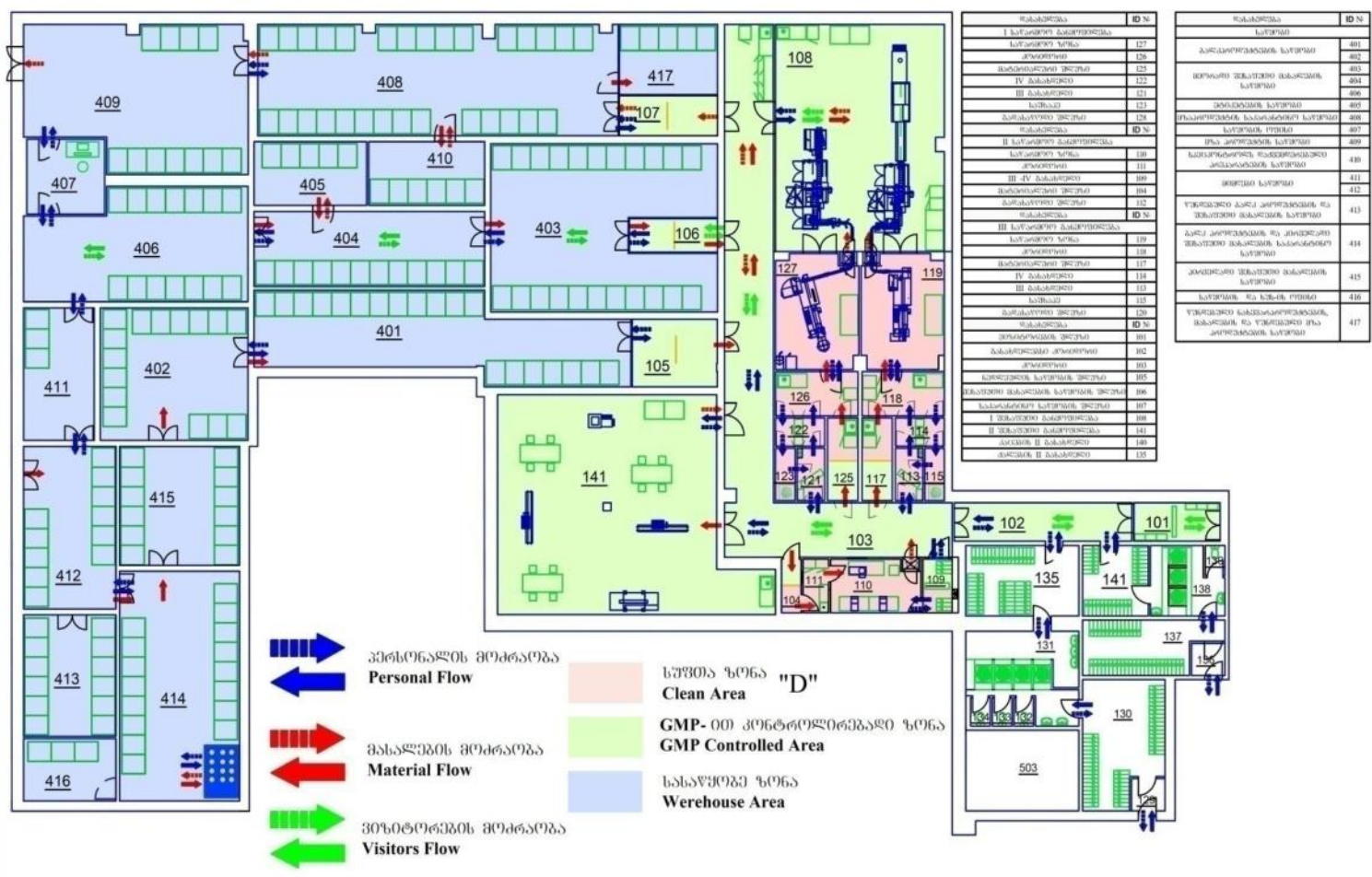
Manufactured Quantities (In Boxes)



Production & Warehouse



შპს "ავერსი-რაციონალი"-ს წარმოების და საწყობის სქემა მასალების და პერსონალის მიმოქცევაში
Lay out of production and storage areas of "Aversi-Rational" including the material and personnel flows



Production & Warehouse



- **Facilities are designed and equipped in accordance with the requirements of ISO 9001, GMP EU & cGMP FDA**
- **AVERSI-RATIONAL owns high quality and modern equipment & engineering systems supplied by renowned and modern equipment manufacturers from USA, Italy, England, Germany and Japan**

Production & Warehouse



- There are 3 types of areas in Manufacture:
 1. Clean area „D”
 2. Controlled area
 3. Unspecified areas
- Controlling and monitoring of the environmental conditions (temperature, humidity, differences in pressure) are carried out permanently





Production & Warehouse







Quality control



QUALITY CONTROL

Physical-Chemical Control

In-coming control

In-process control

Out-going control

Archiving the samples

Stability study

Working with registration samples

Development of new methods

Microbiological Control

In-coming control

Out-going control

Air monitoring

Water monitoring

Surfaces monitoring

Personnel monitoring



Quality control Laboratory



Area : $\approx 750 \text{ m}^2$

Employees : ≈ 35



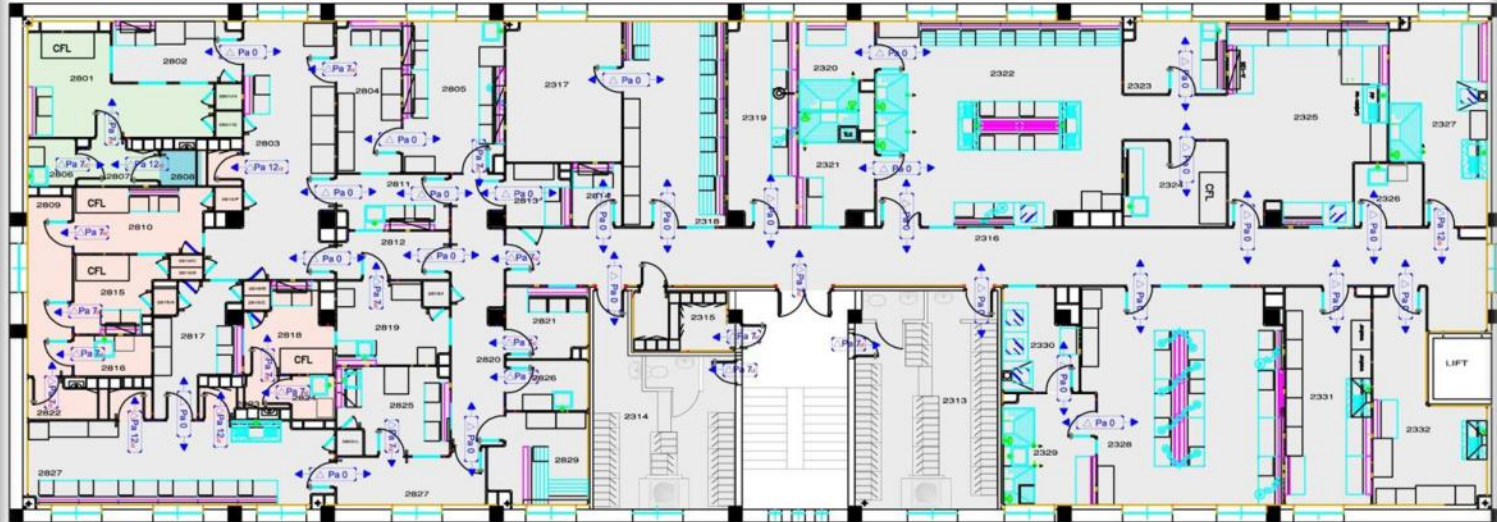


Quality control Laboratory



III Floor

მასშტაბი/Scale 1 :190



- B ზონა (Grade B)
- C ზონა (Grade C)
- D ზონა (Grade D)
- კონტროლირებადი ზონა (Controlled area)
- მაღალი წნევის მხარე (High pressure side)
- [Pa 0] - სათვალვეს შორის წნევის სხვაობა არ არის რეგულირებული (The differential pressure not specified)

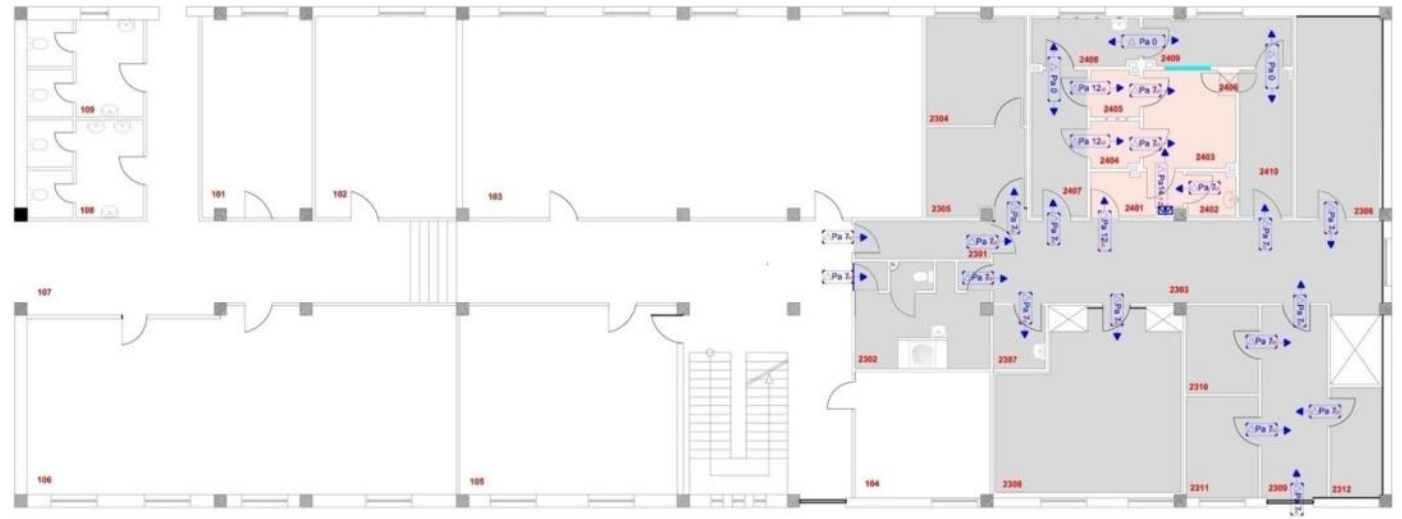


Quality control Laboratory



I Floor

მანშტაბი/Scale 1 :190



- D ჯიშის (Grade D)
- კონტროლირებადი ჯიშის (Controlled area)
- მაღალი წნევის მხარე (High pressure side)
- [Pa 0] - სპეციფიკაციის შენახვის წნევის სხვაობა არ არის მითითებული (The differential pressure not specified)



Quality control Laboratory



- **Areas are arranged and equipped in accordance with International Standards of ISO 9001, GMP EU & cGMP FDA requirements by the project of European company**
- **High quality and modern building materials have been provided by renowned European manufacturers (Switzerland, Spain, Italy, Denmark and others...)**



Quality control Laboratory



Laboratory is equipped with modern high quality equipment:

- **Liquid and gas chromatographs, infrared spectrometer (AG Technologies, USA)**
- **Ultraviolet spectrophotometer (Shimadzu, Japan)**
- **Different types of testers and equipment (Erweka, IKA, Binder, Germany)**
- **Analytical Balances (Sartorius, Germany)**
- **PH-Meters (Mettler Toledo, Switzerland, Sartorius, Germany)**



Quality control Laboratory



- **Laboratory uses high quality American and European reagents of the companies: Sigma-Aldrich (USA) and Applichem (Germany), also reference standards of American, European and British Pharmacopeia**

- **Controlling and monitoring of the environmental conditions (temperature, humidity, differences in pressure) are carried out permanently by the automatic system as well**



Quality control Laboratory



**In 2010, 2012 & 2013
AVERSI-RATIONAL
Laboratory
successfully passed the
international
competition in
UKRAINE
„Program of
Professional Testing“
by 5 methods of
analysis**



Quality control Laboratory



**In 2013
AVERSI-RATIONAL
Laboratory successfully
passed the International
(Strasbourg, France, EDQM)
competition in
„Proficiency Testing Scheme
Study“
in Liquid Chromatography**





Quality control Laboratory



**From the year 2014
Laboratory got the
accreditation
according standard
ISO 17025:2010**



Quality Assurance:



Registration



In order to assure the quality of products under registration:

- **Assessment and periodic monitoring of bulk product suppliers**
- **Identity confirmation studies of Original products (bioequivalence in Vivo and/or in Vitro and comparative clinical studies)**

Validation



In order to assurance the quality and stability of our product and processes:

- **Primary and periodic regularly conducted validation of all relevant devices, equipment, systems, methods & processes**
- **Obligatory revalidation, in case of major or critical changes**

Qualification of Staff



- **High Pharmaceutical, Medical, Chemical Education**
- **8 PhDs in corresponding Fields**
- **11 employees are owned status as quality management system auditors by the German company TÜV SÜD**

Trainings



In order to assurance the adequate number of personnel with satisfactory level of qualification:

- **Complex system of Personnel recruitment**
- **Complex system of personnel training (primary, periodic, special, extreme & external trainings)**
- **„AVERSI-RATIONAL“ actively takes part in many different local or international trainings, seminars, conferences, exhibitions and competitions**



In order to avoid the contamination of product:

- **Primary and periodic medical examinations of all personnel**
- **Daily control of hygiene and health of personnel**
- **Systematic cleaning and disinfection procedures of all areas and equipment**
- **Strictly defined rules of material and personnel movement**

Documentation



In order to ensure the evidence and confirmation of the quality of manufactured products:

- **Management of existed \approx 4000 documents of internal & external origin**
- **Forming and completely evaluation of each Batch Manufacturing Record**
- **Forming and completely evaluation of each Annually Product Quality Review (PQR)**



Changes, Deviations & CAPA



In order to assurance the stability and reliability of our product:

- **Management of all types of changes (minor, major and critical)**
- **Full and objective investigation of all deviations**
- **Planning of corresponding CAPAs and evaluation of their adequacy & sufficiency**



Risk Management



PREVENTION
of the potential problems and defects is
the most preferable activity of the
company
„Aversi-Rational”,
Therefore we have implemented the
effective system of Risk management
and analysis.



Internal & External Audits:



In order to assurance the stability and reliability of our product:

- **Preparing and carrying out internal quality system Audits in all departments of the company**
- **Conducting and accompanying external inspections & Audits**

Customer Satisfaction



The most important aim of the company is to satisfy all desires and expectations of our customers, therefore in order to reach this aim we have implemented:

- **Several types of customer polling programs permanent monitoring of our medicaments**
- **Permanent monitoring of therapeutic effects and adverse reactions of our medicaments**
- **Operative management system of all received complaints from our customers**

Quality Policy



**Quality is the basic task for
each staff member of our
company!**



Continual Improvement



- **The main reason of „Aversi-Rational“ success is the continual working for improvement that is approved by the successfully realized projects of it**

- **Nowadays, we are implementing unique computerized program - „1C Pharma-Systems“, which provides operative and effective management of all processes in our company**

Next Steps



- **Increase the EXPORT of our product in foreign Markets**
- **Expansion and developing of production lines and Increasing the capacity and productivity of the manufacture**



Georgian-African Business Association

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Thank you for Attention!

Wish you Health and Peace of Mind!

