



Have a Healthy Life
www.dorsadarou.com

Company Profile

Dorsa Pharmaceutical Co. as a national awarded science-led company, is the main member of Tavan Pharmaceutical Holding (**TPH**). The uniqueness of this pharmaceutical holding is the complete value chain it can offer to its partners and customers, both nationally and internationally.

Tavan Institute, is another strong wing and active member of **TPH** with its highly qualified R&D team and close alliance with university professors, it can support Under-license partnerships by its state-of-the-art analytical and formulatory laboratories. This laboratory has extended experience in preparing the entire regulatory documentation requirements based on Iranian FDA and MOH guidelines. The institute had carried out and compiled more than 40% of all new DMF and CTD files for drug molecules added to the Iranian Drug List (IDL) during the past 10 years. In addition, more than 200 bio-equivalency tests have been established by this laboratory since the beginning of its operation. For this important reason, Iran FDA (IFDA) has awarded this laboratory as one of the few IFDA-Accredited national laboratories, granting it to carry out quality control tests on foods, drugs and cosmetics and has issued GLP certificate to this institute.

Recpharma Company (Notarkib Co.) is a TPH Bio-tech member of the group, involved in Human DNA-Recombinant products. **Gamma Interferon** and **Erythropoietin α** are two main products manufactured in Recpharma with close collaboration by an Austrian Biotech establishment.

With all this support, **Dorsa** aim at organic growth from its own resources with simultaneous openness to partnership and strategic alliances in research and production. Based on our unique position as a research-based drug company, accredited by Vice-Presidency of Science and Technology, and also as a very few holder of cGMP Certificate in Iran (issued based on PIC/S new guidelines) for General Solid Dosage Forms and Ready to Press Granule production line (various forms of Nitroglycerine API) among all other Iranian pharmaceutical companies, we are proud to deliver professional service and products to our partners and customers in and outside the country.

Recognizing the challenges facing health care systems today, we collaborate with regulatory authorities and customers such as health care providers and payers, so that those in need can access our medicines at an affordable price.

Professional, ethical and compliant, we hold ourselves accountable to deliver value to our customers and shareholders.

Quality: We have learned to provide high quality pharmaceutical products and services, through a decade of persisting to produce high quality finished-form products and purified API bulk (Nitroglycerin API, Nitrodor®). Since quality for us means more than just GMP compliance, we have a comprehensive set of health, safety and environmental policies in place, which has been recognized by national authorities and customers on various occasions.

Reliability: Based on our management records, our shareholders and board of director's annual reports, as well as our customer testimonies, they all testify that we are a reliable and loyal long-term partner in this industry.

Dorsa is a reliable partner for long-term partnership in Iran pharmaceutical market and strategic business collaborations. We, together, can deliver the right solutions at the right time, building long term relationships with our partners for mutual benefits. While working diligently, we do not give up even when challenged, pursuing innovation in all that we do.

We are humbled by the opportunity we face to change lives.

Sustainability: We are looking for sustainability by pursuing economy-scale performance, environmental friendly processes and social responsibility campaigns, which can benefit the most for our partners and customers. In simple words, we seek to create value in three dimensions: **People, Planet and Profit**. We are pioneers of eco-friendly technologies and processes for production of Nitroglycerin sustained release granule, which is also observed for our finished-form products proven by several innovations in Green technology.

This has been the base for assessment and awarding Dorsa Pharmaceutical Co. as a National science-led company in 2014.

We are committed to our employees, for diversity and equal opportunity and environmental sustainability.

Production Lines

Dorsa Pharmaceutical Co. began in 1998, manufacturing two product types: **API** and **Finished-form pharmaceutical products** and after obtaining the necessary permits and marketing authorizations, it became fully operational in 2009. **Dorsa is interested in expanding cooperation with other international companies around the world.** Our company has the capability of manufacturing different diluted forms of **Nitroglycerin API bulk (Nitrodor®)** for use in different finished dosage forms. **Nitroglycerin API bulk (Nitrodor®)** can be supplied as granules in anhydrous lactose form for tablet pressing or diluted in ethanol for injection products.

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Nitrodor® can also be supplied diluted in Miglyol for sub-lingual pearls and inhalation spray. **Nitrodor®** can be used for patch and ointment preparations too.

Dorsa constantly updates its GMP standards, abiding current guidelines and legislation enforced by Iran FDA and in accordance with PIC/S international standards, to proudly keep its cGMP Certificate valid.

Certificates

Iran FDA (MOH) has become an official member of PIC/S since January 2018.

Since the start of this membership and stricter standards enforced, very few local manufacturers managed to obtain Iran FDA GMP certificate, and we are proud to be one of them.

List of Certificates obtained by Dorsa:

- ✓ GMP: (2018) - Iran FDA Certificate for General Solid Dosage and Suspension Forms issued based on new PIC/S guidelines .
- ✓ cGMP: (2018) - Iran FDA Certificate for Pharmaceutical Raw Material (API) issued based on new PIC/S guidelines.
- ✓ National Customer Care Trophy: (2017)
- ✓ MITEC, ICS Group International: (2015)
- ✓ ISO9001: (2008)
- ✓ OHSAS18001: (2007)
- ✓ ISO14001: (2004)

Export Agenda

All our listed products in finished-forms as well as Nitroglycerin API bulk (Nitrodor®) are available for Export markets. API of Nitroglycerin (Nitrodor®) in various forms is available for Export according to your finished form requirements.

We can re-design our product packaging and translate Patient Information Leaflets (PIL) and product brochures according to your regional requirements.

We are active in Africa, CIS, MENA, ASEAN and Eurasian countries and we aim to reach more countries in these regions and beyond as part of our **Export Expansion 2020 Agenda**

We are prepared to **Out-license** our products under our brand names for your local production facilities, allowing you to take advantage of local manufacturing governmental support. This Out-licensing can start with secondary packaging moved to primary packaging, followed by pre-mix bulk supply in the final phase.

Dorsa is also a fully integrated, in-house Contract Manufacturing Organization (CMO) and Contract and Development Manufacturing Organization (CDMO), committed to delivering a better experience for our clients.

We can arrange to manufacture your designated finished-form products on our production lines using our in-house facilities and professional team members. Our production expertise together with collaboration of **Tavan Institute**, enable us to make formulation process and bio-equivalency testing possible, allowing **Dorsa** to provide complete formulation package and testing process of your finished-form drug product, scheduled to be Contract-manufactured or CDMO at our production site, available to all local and global commercial customers.

We are also capable to launch and market your branded medicinal product in Iranian market, either under your brand name as an Under-license deal or as a new brand name defined under Joint-venture cooperation.

Target regions for Export market:

- ✓ **Europe**
- ✓ **Africa**
- ✓ **South America**
- ✓ **MENA**
- ✓ **CIS**
- ✓ **Eurasia**
- ✓ **ASEAN**

Product Portfolio: Therapeutic Groups and Pharmaceuticals

Category	Generic Name	ATC Code	Trade Name	Dosage Form & Strength
Cardiovascular System	Nitroglycerin	C01DA02	Dorocontin [®]	2.6 mg & 6.4 mg Extended Release Tablets
	Atorvastatin	C10AA05	Lipi-Cut [®]	20 mg & 40 mg Tablets
	Losartan	C09CA01	-	25 mg & 50 mg Tablets
	Rosuvastatin	C10AA07	-	5 mg, 10 mg, 20 mg, 40 mg & 100 mg Tablets
	Metoprolol Tartrate	C07AB02	-	50 mg Tablets
	Propranolol	C07AA05	-	10 mg, 20 mg & 40 mg Tablets
Antibacterial for Systemic Use	Azithromycin	J01FA10	Azithrodor [®]	250 mg & 500 mg Capsules 100 mg & 200 mg/5 ml Powder for Oral Suspension
	Clarithromycin	J01FA09	Claridor [®]	250 mg & 500 mg Coated Tablets 125 mg & 250 mg/5 ml Powder for Oral Suspension
	Ciprofloxacin	J01MA02	-	250 mg & 500 mg Coated Tablets
	Levofloxacin	J01MA12	-	500 mg Tablets
Gastric Acid Related Disorders	Lansoprazole	A02BC03	Lansidor [®]	15 mg & 30 mg Delayed Release Capsules
	Esomeprazole	A02BC05	Nexive Forte [®]	20 mg & 40 mg Delayed Release Capsules
	Omeprazole	A02BC01	-	20 mg Delayed Release Capsules
	Pantoprazole	A02BC02	-	20 mg & 40 mg Delayed Release Capsules
Respiratory System	Montelukast	R03DC03	Asmont [®]	5 mg Chewable Tablets- 10 mg Film-Coated Tablets
	Cetirizine	R06AE07	Rhinizine [®]	10 mg Tablets
Diabetes	Pioglitazone	A10BG03	Diador [®]	15 mg & 30 mg Tablets
	Metformin	A10BA02	Glucodor [®]	500 mg Tablets
	Sitagliptin	A10BH01	-	25 mg & 50 mg Tablets
	Glibenclamide	A10BB01	-	5 mg Tablets
Nervous System	Zolpidem Tartrate	N05CF02	Zolpra [®]	5 mg & 10 mg Film-Coated Tablets
	Chlordiazpoxide	N05BA02	-	5 mg & 10 mg Tablets
	Sertraline	N06AB06	-	50 mg & 100 mg Tablets
	Gabapentin	N03AX12	-	100 mg, 300 mg & 400 mg Tablets
	Acetaminophen Caffeine Ibuprofen		Dorofen [®]	325/40/200 mg Capsules
Nutritional Supplements	Folic Acid plus Iodine		Iodofolic [®]	Folic Acid 500 µg/ Iodine 150 µg
	Folic Acid plus Iodine & 15 Vitamins/Minerals		iVita [®]	Folic Acid 600 µg/ Iodine 150 µg, Vit.E - 15 mg, Vit.D - 15 µg, Vit.C - 90 mg, Vit. B1 - 4 mg, Vit.B2 - 3 mg, Vit.B3 - 20 mg, Vit.B6 - 10 mg, Vit.B12 - 6 µg, Biotine - 150 µg, Pantothenic acid - 6 mg, Zinc - 15 mg, Iodine - 150 µg, Copper - 1 mg, Selenium - 55 µg, Magnesium - 100 mg, Iron - 27 mg
	Vitamin D ₃	A11CC05		1200 IU and 2000 IU Tablets
Urologicals	Sildenafil	G04BE03	Vigrodit [®]	50 mg & 100 mg Tablets
Musculo-Skeletal System	Celecoxib	M01AH01	Doroxib [®]	200 mg Capsules
Antiemetics	Aprepitant	A04AD12		80 mg & 125 mg Tablets

Pharmaceutical Semi Finished Materials List

Trade Name	Name of Product
Nitrodor®	Diluted Nitroglycerin 10% w/w in Anhydrous Lactose
-	Nitroglycerin granules 1.6%, w/w for E.R Tablets
-	Diluted Nitroglycerin 5% w/w in Ethanol (for Injection)
-	Nitroglycerin granules 5%, w/w in Miglyol
-	Diluted Nitroglycerin 0.35%, w/w in Miglyol (for Sublingual Pearls)
-	Diluted Nitroglycerin 0.4%, w/w in Miglyol (for Inhalation Spray)

Pipeline Products

Category	Generic Name	ATC Code	Dosage Form
Gastro-intestinal & Metabolism	Hyoscine	A03BB01	Tablets
	UDCA (Ursodeoxycholic acid)	A05AA02	Capsules
	Bismuth subcitrate	A02BX05	Tablets
	Domperidone	A03FA03	Tablets
	Ondansetron	A04AA01	Tablets
Antibacterials for Systemic Use	Metronidazole	J01XD01	Tablets
	Linezolid	J01XX08	Tablets
Urologicals	Tadalafil	G04BE08	Tablets
	Dapoxetine	G04BX14	Tablets
CNS	Duloxetine EC	N06AX21	Capsules
Musculo-Skeletal System	Diclofenac SR	M01AB05	Tablets
Nutritional Supplements	Vitamin B1 (HCl)	A11DA01	Tablets
Hyperkalemia	Sevelamer carbonate	V03AE02	Tablets

Dorocontin[®] • Cardiovascular System

- Brand Name:** Dorocontin[®]
Generic Name: Nitroglycerin
Dosage Form: F. C. Tablets
Strength: 20 & 50 mg
Packaging: Single Unit Dose Blister Package
100 Tablets (10 x 10)
Indication: Angina pectoris, acute &
chronic (treatment & prophylaxis)



Single Unit Dose Blisters (Alu-Alu foil)
Package 100 Tablets (10 x 10)



Dorocontin[®] • Cardiovascular System

- Brand Name:** Dorocontin[®]
Generic Name: Nitroglycerin
Dosage Form: Extended Release Tablets
Strength: 2.6 & 6.4 mg
Packaging: Bottle of 50 Tablets
Indication: Angina pectoris, acute & chronic (treatment & prophylaxis)



Losartan[®] • Cardiovascular System

Brand Name: -

Generic Name: Losartan

Dosage Form: F. C. Tablets

Strength: 20 & 50 mg

Packaging: Single Unit Dose Blister Package
100 Tablets (10 x 10)

Indication: Hypertention (treatment)



Lipi-Cut® • Cardiovascular System

- Brand Name:** Lipi-Cut®
Generic Name: Atorvastatin
Dosage Form: F. C. Tablets
Strength: 20 & 40 mg
Packaging: Single Unit Dose Blister Package
30 Tablets (3×10)
Indication: Hyperlipidemia (treatment)



Azithrodor® • Antibacterials for Systemic Use

- Brand Name:** Azithrodor®
Generic Name: Azithromycin
Dosage Form: Powder for Oral Suspension
Strength: 100 & 200 mg/5ml
Packaging: Available in 15 & 30 mg bottles
Indication: Bronchitis, Bacterial exacerbations, acute Otitis media, Cervicitis, Urethritis, Chancroid, Mycobacterium avium complex, Pelvic inflammatory, Pharyngitis, Tonsillitis, Pneumonia, Community-acquired and skin and soft tissue infections (treatment)



Azithrodor® • Antibacterials for Systemic Use

- Brand Name:** Azithrodor®
Generic Name: Azithromycin
Dosage Form: Capsules
Strength: 250 & 500 mg
Packaging: Single Unit Dose Blister Package 6 Capsules (1×6)
Indication: Bronchitis, Bacterial exacerbations, acute Otitis media, Cervicitis, Urethritis, Chancroid, Mycobacterium avium complex, Pelvic inflammatory, Pharyngitis, Tonsillitis, Pneumonia, Community-acquired and skin and soft tissue infections (treatment)



Claridor® • Antibacterials for Systemic Use

- Brand Name:** Claridor®
Generic Name: Clarithromycin
Dosage Form: Powder for Oral Suspension
Strength: 125 & 250 mg/5ml
Packaging: Available in 100ml bottles
Indication: Bronchitis, Bacterial exacerbations, acute Otitis media, Cervicitis, Urethritis, Chancroid, Mycobacterium avium complex, Pelvic inflammatory, Pharyngitis, Tonsillitis, Pneumonia, Community-acquired and skin and soft tissue infections (treatment)



Claridor® • Antibacterials for Systemic Use

- Brand Name:** Claridor®
Generic Name: Clarithromycin
Dosage Form: Tablets
Strength: 250 & 500 mg
Packaging: Single Unit Dose Blister Package 30 Tablets (5×6)
Indication: Bronchitis, Bacterial exacerbations, acute Otitis media, Cervicitis, Urethritis, Chancroid, Mycobacterium avium complex, Pelvic inflammatory, Pharyngitis, Tonsillitis, Pneumonia, Community-acquired and skin and soft tissue infections (treatment)



Pantoprazole® • Gastric Acid Related Disorders

Brand Name: -

Generic Name: Pantoprazole

Dosage Form: Capsules

Strength: 20 & 40 mg

Packaging: Single Unit Dose Blister Package 28 Capsules (2×14)

Indication: Gastroesophageal reflux disease [GERD] (treatment & prophylaxis), Duodenal ulcer (treatment), Duodenal ulcer, Helicobacter pylori-associated (treatment), Gastric ulcer (treatment) Zollinger, Ellison Syndrome, NSAID Induced gastric ulcer



Omeprazole • Gastric Acid Related Disorders

- Brand Name:** -
Generic Name: Omeprazole
Dosage Form: Capsules
Strength: 20mg
Packaging: Bottle of 14 Tablets
Indication: Gastroesophageal reflux disease [GERD] (treatment & prophylaxis), Duodenal ulcer (treatment), Duodenal ulcer, Helicobacter pylori-associated) treatment, Gastric ulcer (treatment), Zollinger, Ellison Syndrome, NSAID Induced gastric ulcer



Nexive[®] Forte • Gastric Acid Related Disorders

- Brand Name:** Nexive[®] Forte
Generic Name: Esomeprazole
Dosage Form: Capsules
Strength: 20 & 40 mg
Packaging: Single Unit Dose Blister Package 30 Capsules (3×10)
Indication: Gastroesophageal reflux disease [GERD] (treatment & prophylaxis), Duodenal ulcer (treatment), Helicobacter pylori-associated, Gastric ulcer (treatment) Zollinger, Ellison Syndrome, NSAID Induced gastric ulcer



Lansidor® • Gastric Acid Related Disorders

- Brand Name:** Lansidor®
Generic Name: Lansoprazole
Dosage Form: Capsules
Strength: 15 & 30 mg
Packaging: Single Unit Dose Blister Package 30 Capsules (3×10)
Indication: Gastroesophageal reflux disease [GERD] (treatment & prophylaxis), Duodenal ulcer (treatment), Helicobacter pylori-associated, Gastric ulcer (treatment) Zollinger, Ellison Syndrome, NSAID Induced gastric ulcer



Diador[®] • Diabetes

- Brand Name:** Diador[®]
Generic Name: Pioglitazone
Dosage Form: Tablets
Strength: 15 & 30 mg
Packaging: Single Unit Dose Blister Package 30
Tablets (3×10)
Indication: Diabetes, type 2 (treatment)



Glucodor[®] • Diabetes

- Brand Name:** Glucodor[®]
Generic Name: Metformin
Dosage Form: Tablets
Strength: 500 mg
Packaging: Single Unit Dose Blister Package 100
Tablets (5×20)
Indication: Diabetes, type 2 (treatment)



Rhinizine® • Respiratory System

- Brand Name:** Rhinizine®
Generic Name: Cetirizine
Dosage Form: Tablets
Strength: 10 mg
Packaging: Single Unit Dose Blister Package 30
Tablets (3×10)
Indication: Seasonal or perennial allergic
rhinitis, Chronic urticaria



Asmont[®] • Respiratory System

- Brand Name:** Asmont[®]
Generic Name: Montelukast
Dosage Form: Tablets
Strength: 5 & 10 mg
Packaging: Single Unit Dose Blister Package 30 Tablets (3×10)
Indication: Symptomatic relief of seasonal allergic rhinitis in patients with Asthma, (prophylaxis and treatment) Exercise, Induced Bronchospasm (prophylaxis)



Dorofen® • Nervous System

- Brand Name:** Dorofen®
Generic Name: Acetaminophen/Caffeine/Ibuprofen
Dosage Form: Capsules
Strength: 325/40/200 mg
Packaging: Single Unit Dose Blister Package 30 Capsules (3×10)
Indication: Anti-rheumatic, Analgesic, Antipyretic, Anti-dysmenorrheal Acute pain



Doroxib[®] • Musculo-Skeletal System

- Brand Name:** Doroxib[®]
Generic Name: Celecoxib
Dosage Form: Tablets
Strength: 200 mg
Packaging: Single Unit Dose Blister Package 30 Capsules (3×10)
Indication: Rheumatoid or osteoarthritis (treatment)
Acute pain Ankylosing Spondylitis
Rheumatoid Arthritis



Vigrodit® • Urologicals

- Brand Name:** Vigrodit®
Generic Name: Sildenafil
Dosage Form: Tablets
Strength: 50 & 100 mg
Packaging: Single Unit Dose Blister Package 4 Tablets (1×4)
Indication: Treatment of Erectile dysfunction.



Zolpra[®] • Nervous System

Brand Name: Zolpra[®]

Generic Name: Zolpidem

Dosage Form: Tablets

Strength: 5 & 10 mg

Packaging: Single Unit Dose Blister Package 30
Tablets (3×10)

Indication: Insomnia (short-term treatment)



iVita® • Nutritional Supplements

- Brand Name:** iVita®
- Generic Name:** Folic Acid plus Iodine & 15 Vitamins/Minerals
- Dosage Form:** Tablets
- Strength:** Folic Acid 600 µg
Iodine 150 µg plus 15 Vitamins/
Minerals
- Packaging:** Bottle of 30 Tablets
- Indication:** iVita® is a combination of iodine and folic acid, and 15 other beneficial nutrients needed for all stages of pregnancy and early motherhood. An ideal supplement for preconception, through pregnancy and breastfeeding.



Iodofolic® • Nutritional Supplements

- Brand Name:** Iodofolic®
Generic Name: Folic Acid plus Iodine
Dosage Form: Tablets
Strength: Folic Acid 500 µg
Iodine 150 µg
Packaging: Single Unit Dose Blister Package 100
Tablets (10×10)
Single Unit Dose Blister Package 30
(3×10) Tablets
Indication: Iodofolic® is a combination of
iodine and folic acid, both important
for preconception, pregnancy and
breastfeeding.





Newly Launched Products



Newly Launched

- **Rosuvastatin** 5mg, 10mg, 20mg, 40mg & 100mg Tablets
- **Ciprofloxacin** 250mg & 500mg Tablets
- **Sitagliptin** 25mg & 50mg Tablets
- **Glibenclamide** 5mg Tablets
- **Losartan Potassium** 25mg & 50mg Tablets
- **Levofloxacin** 500mg Tablets
- **Metoprolol Tartrate** 50mg Tablets
- **Tamsulosin** 0.4 mg Capsules
- **Dapoxetine** 30mg & 60mg Tablets

Newly Launched

- **Chlordiazpoxide** 5mg & 10mg Tablets
- **Aprepitant** 80mg & 125mg Capsules
- **Sertraline** 50mg & 100mg Tablets
- **Propranolol** 10mg, 20mg & 40mg Tablets
- **Gabapentin** 100mg, 300mg & 400mg Tablets
- **Azithromycin Suspension** 200mg/5ml in 30 ml Bottle
- **Vitamin D₃** 1200 IU & 2000 IU Tablets
- **Dapoxetine** 30mg & 60mg Tablets
- **Nitroglycerin Spray** 0.4mg

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SCAN ME

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