REINE

Devoted to Life

ANVISA, CEP & WHO-GMP Accredited API Company



Committed to improving lives through **QUALITY APIS**



Established in 1993 as a small chemical manufacturing firm in Ankleshwar, Reine is now one of the leading manufacturers of select APIs. Our global performance is being multiplied by our leadership excellence and teamwork of our employees.

From select APIs & its advance intermediates, we are manufacturing our products with facilities spread in more than 6,000 sq. mt. area. Facilities at our existing unit comprises of production facilities, product development facilities, R&D, QC-QA Lab, technology transfer & administration building.

WHO-GMP

KOREA MFDS

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API Products - List

Sr. No.	Product	Therapeutic Category	Pharmacopoeia	Regulatory Status				
				CEP	MFDS	ANVISA	EDMF	DMF
Products								
01	Amiodarone HCl	Anti-Arrhythmic	IP, BP, EP, USP	-	-	-	-	√
02	Apixaban	Anti-coagulant	IH	-	-	-	-	√
03	Atorvastatin Calcium	Cardiovascular	IP, BP, EP, USP	SUBMITTED	-	ACCREDITED	-	√
04	Baclofen	Anti-spasmodic	IP, BP, EP, USP	-	-	-	-	√
05	Benzocaine	Anaesthetics	BP, EP, USP	ACCREDITED	-	ACCREDITED	-	√
06	Bilastine	Anti-Allergic	IP/IH	-	-	-	-	√
07	Deferasirox	Iron Chelator	IP/IH, BP, EP	-	-	-	-	√
08	Deferiprone	Iron Chelator	BP, EP	-	-	-	-	√
09	Ethambutol HCl	Anti-Tubercular	IP, BP, EP, USP	-	-	-	-	√
10	Erdosteine	Mucolytic Agent	IH	-	ACCREDITED	ACCREDITED	ACCREDITED	√
11	Febuxostat	Dipeptidyl peptidase-4	IH	-	-	-	-	√
12	Itopride HCl	Gastro Prokinetic Agent	IP/IH	-	-	-	-	√
13	Labetalol HCl	Anti-Hypertension	IP, BP, EP, USP	-	-	-	-	√
14	Letrozole	Anti-Estrogen	IP, BP, EP, USP	-	-	-	-	√
15	Metoprolol Succinate	Anti-Hypertension	IP, BP, EP, USP	ACCREDITED	-	ACCREDITED	-	√
16	Metoprolol Tartrate	Anti-Hypertension	IP, BP, EP, USP	ACCREDITED	-	ACCREDITED	-	√

CEP | MFDS | ANVISA | EDMF

API Products - List

Sr. No.	Product	Therapeutic Category	Pharmacopoeia	Regulatory Status				
				CEP	MFDS	ANVISA	EDMF	DMF
Products								
17	Minoxidil	Anti-Hypertension	IP, BP, EP, USP	-	-	-	-	√
18	Mirogabalin besylate	Neuropathic Pain	IH	-	-	-	-	√
19	Phenylbutazone	NSAID	BP, EP, USP	ACCREDITED	-	ACCREDITED	-	√
20	Pregabalin	Anti-Epilepsy	IP, BP, EP, USP	SUBMITTED	-	ACCREDITED	-	√
21	Rosuvastatin Calcium	Cardiovascular	IP, BP, EP, USP	ACCREDITED	ACCREDITED	ACCREDITED	-	√
22	Sitagliptin Phosphate Monohydrate	Dipeptidyl peptidase-4	IP, BP, EP, USP	-	-	-	-	√
23	Teneligliptin HBr	Anti-Diabetic	IP	-	-	-	-	√
24	Teneligliptin HCl	Anti-Diabetic	IH	-	-	-	-	√
25	Torsemide	Anti-Hypertension	IP, BP, EP, USP	-	-	-	-	√
26	Trazodone HCl	Anti-Depressant	IP, BP, EP, USP	-	-	-	-	√
Pipeline Products								
27	Bempedoic Acid	-	IH	-	-	-	-	-
28	Edoxaban Tosylate	-	IH	-	-	-	-	-
29	Indapamide	-	USP	-	-	-	-	-
30	Tegoprazan	-	IH	-	-	-	-	-
31	Ursodiol	-	IP	-	-	-	-	-

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Reine Lifescience respects patent laws and conventions of pharmaceuticals as applicable in different countries.
API /Substances covered by patent are not offered to the countries where the patent law is in force.
However, the final responsibility lies with the customer.

*CEP Approval for

- Rosuvastatin Calcium
- Metoprolol Succinate
- Metoprolol Tartrate
- Phenylbutazone
- Benzocaine

*CEP Applied for

- Pregabalin
- Atorvastatin Calcium

*MFDS Korea

- Erdosteine
- Rosuvastatin Calcium

*ANVISA Approval for

- Atorvastatin Calcium Trihydrate
- Benzocaine
- Erdosteine
- Metoprolol Succinate
- Metoprolol Tartrate
- Phenylbutazone
- Phenylbutazone Calcium
- Pregabalin
- Rosuvastatin Calcium

***ANVISA, CEP & WHO-GMP approved facility**



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