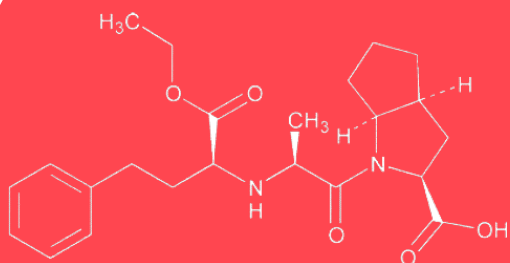


Ramipril



Ramipril API

Chemical Name: (2S,3aS,6aS)-1[(S)-N [(S)-1-Carboxy-3-phenylpropyl] alanyl] octa hydrocyclopenta [b]pyrrole-2 carboxylic acid, 1~-ethyl ester.

Chemical Formula: C₂₃H₃₂N₂O₅

Ramipril is an angiotensin-converting enzyme (ACE) inhibitor indicated for treating hypertension to lower blood pressure. ACE inhibitors inhibit the angiotensin-converting enzyme (ACE) actions, thereby reducing the production of angiotensin II and decreasing the breakdown of bradykinin. The decrease in angiotensin II results in relaxation of arteriole smooth muscle leading to a reduction in total peripheral resistance, reducing blood pressure as the blood is pumped through widened vessels.

Ramipril works by lowering blood pressure and reducing the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. In addition, Ramipril, in combination with thiazide diuretics, is used to treat hypertension.

Dr. Reddy's API Offering

Dr. Reddy's is among the earliest generic API manufacturers globally to file the USDMF for Ramipril API. In addition to the USDMF, considering the requirement of country-specific regulatory filings, we have diversified our DMFs with regulatory filing in countries like Europe (CEP), Canada, China, Taiwan, and Israel.

Timelines of FDA Approvals Across Indications for Ramipril

On October 4, 2000, the FDA approved the original dosage form, i.e., Altace® capsules, to reduce the risk of myocardial infarction, stroke, and cardiovascular diseases ^[1].

Specifications and Impurity Profile

S.No	Specifications	Result
1	API assay	> 99.5 % (meets the USP monograph specification for Ramipril).
2	Genotoxic impurities	Controlled below Threshold of Toxicological Concern (TTC) - Multiple steps with stringent process parameters to control the impurity levels in the product.
3	Nitrosamine impurities	Our API is free from possible nitrosamines as per our complete chemistry assessment of the synthesis route of KSM, intermediates, reagents, and solvents.
4	Storage conditions	At 25°C room temperature
5	Particle size distribution	D90 <150 µm
6	Elemental impurities	< Specifications in accordance with ICH Q3D

Manufacturing and Supply Assurance:

We manufacture Ramipril at our cGMP API manufacturing facilities, successfully inspected by international regulatory authorities.

Manufacturing site	Capacity
CTO-3, Bollaram, Jinnaram Mandal Medak District Telangana, India	24 metric tons /Year

- We are well-positioned to meet the global demand for Ramipril API.
- We have reliable KSM suppliers to ensure timely deliveries and adhere to stringent specifications. We are also multi-sourced on our KSMs for a sustainable supply.

Proven Track Record in Drug Product Development

- Dr. Reddy's successfully supplied Ramipril to various customers worldwide, and many customers have successfully filed their dossiers and commercialized it in their respective countries.
- Dr. Reddy's is among the earliest generic API manufacturers globally and filed the USDMF for Ramipril API. In addition, we can provide country-specific regulatory filings in various countries to support global market expansions.

For more information or to order sample quantities of APIs or formulations, log in to our customer service portal [XCEED](#) or contact us at api@drreddys.com.

References:

1. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/019901s060lbl.pdf

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