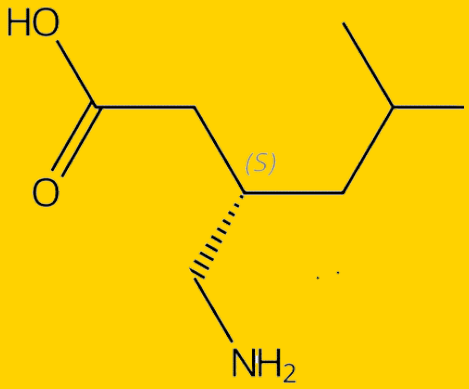
Pregabalin



CAS: 148553-50-8

Pregabalin API

Molecular Weight: 159.23 g/mol

Chemical Name: (3S)-3-(aminomethyl)-5-methylhexanoic acid

Chemical Formula: $C_8H_{17}NO_2$

Pregabalin's precise mechanism of action is not fully understood, but studies suggest that it binds to the alpha2-delta subunit of voltage-gated calcium channels in the central nervous system. This binding modulates the release of excitatory neurotransmitters and prevents the trafficking of the alpha2-delta subunit. Although pregabalin is structurally related to GABA, it does not directly bind to GABA or benzodiazepine receptors [1].

The table below provides the FDA approval timelines of Pregabalin across indications:

Approval Date	Approved Indication
October 12, 2017	Lyrica CR® (pregabalin) extended-release tablets have been approved by the FDA for the treatment of neuropathic pain conditions [2].
June 21, 2012	The FDA has granted approval for Lyrica® to manage neuropathic pain associated with spinal cord injury, following a priority review [2].
June 22, 2007	Lyrica® has become the first drug to receive FDA approval for the treatment of fibromyalgia [2].
December 31, 2004	Pfizer Inc. has developed Lyrica® as a treatment specifically for neuropathic pain [2].
September 2, 2004	Pfizer has issued a statement regarding the regulatory status of Lyrica® [2].

Our API Offering

- Offers **crystalline form-I i.e., Innovator form.**
- The control strategy for the API impurity profile has been designed through **quality-by-design (QbD)** based development.
- Lactam impurity levels are not detected thus able to achieve **USP/ EP compliance** after milling - opening a possibility for a wide range of delivery systems like **dispersible films, oral disintegrating tablets, etc.**

Specifications and Impurity Profile

Specifications	Result
API Assay	• Purity: Not less than **98.0%** and not more than **102.0%** • Chiral purity not less than **99.85%** (undesired isomer limit is not more than 0.15%).
Genotoxic Impurities (GTIs)	All GTIs are controlled below the threshold of **toxicological concern (TTC) limits.**
Nitrosamine Impurities	As per the chemistry assessment, we have evaluated all possible N-Nitroso dialkyl impurities in the Pregabalin manufacturing process. It could have been proven that no N-Nitroso dialkyl impurities are formed.
Elemental Impurities	Specifications in accordance with **ICH Q3D**
Particle Size Distribution (PSD)	We provide customizable PSD options and can match a wide range of particle size requirements: **D (90) - 40 to 550 microns** are possible.
Quality Control	Residual solvents are detected at >100 ppm against ICH limits of around 3000 - 5000ppm.
Stability Data	**6 Months accelerated** and **24 Months long term** stability data are available (Stability program is continuing).
Storage Conditions	Preserve in tight containers. Protect from light and store at 25°C.

DMF Filing and Regulatory Support

Dr. Reddy's is among the earliest generic API manufacturers globally to file the **USDMF** for Pregabalin API. Besides this, we have DMFs available in **CEP, Brazil, Europe, Korea, Russia,** and **China.**

Manufacturing and Supply Assurance

- We manufacture Pregabalin API at our cGMP API manufacturing facility, which was successfully inspected by international regulatory authorities - **WHO GMP, KFDA, PMDA, ANVISA,** and **USFDA**.
- We have **reliable key starting material (KSM)** suppliers to ensure timely deliveries and adherence to stringent specifications.
- Advanced intermediates are manufactured at **qualified strategic partner sites** and can be scaled up to meet commercial requirements.
- A short **lead time of 10 - 90 days** from the date of the purchase order (PO) depending on the quantity, particle size requirement, bulk density requirements, additional test parameters, etc.

Batch size	Capacity
Current API batch size is 225kg.	Large capacity of ~50MT/ annum

Sustainability

- The chemistry used for this product is greener and has less effluent generation compared to the conventional route of synthesis.
- Our API manufacturing plant is a zero-liquid discharge (ZLD) facility, which means that all the effluents generated are treated within premises, and treated water is recycled and reused. We also co-process the final residue from the ZLD facility.
- As a company, we co-process/recycle 99 % of our total hazardous waste and continue to be on course to meet our target of zero hazardous waste to landfill.

Scan this QR Code to contact us:

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References:

1. https://go.drugbank.com/drugs/DB00230
2. https://www.drugs.com/history/lyrica.html

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.**