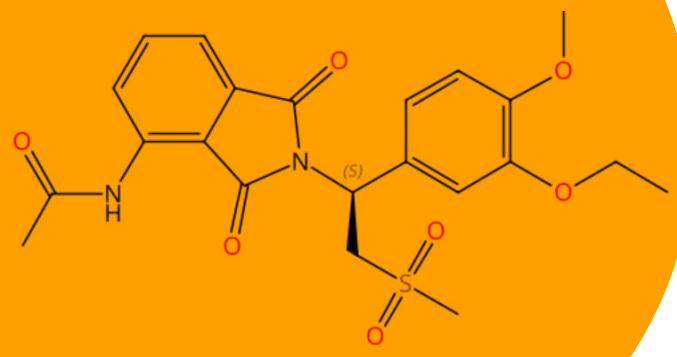
Apremilast API



CAS No: 608141-41-9

Apremilast API

Chemical Name: N-{2-[(1S)-1-(3-Ethoxy-4-methoxyphenyl)-2-(methylsulfonyl)ethyl]-1,3-dioxo-2,3-dihydro-1H-isoindol-4-yl} acetamide.

Chemical Formula: $C_{22}H_{24}N_2O_7S$

Our API Offering*:

- Dr. Reddy's is among the earliest generic API manufacturers globally for Apremilast API and filed the USDMF in September 2016 (Form-B) and June 2017 (Amorphous). Besides this, we have DMF filings in Canada and Brazil.
- Offers the same form as the innovator drug, facilitating successful bioequivalence studies.

Manufacturing and Capacity:

We manufacture Apremilast at our cGMP API manufacturing facility in Vizag (CTO-SEZ), which is successfully inspected by global regulatory authorities, including the US FDA, and is EU GMP certified too.

- The current batch size is 15 kg with plans to scale the API batch size to ~60 kg.
- Control strategy in place for scaling up to 1.5 metric-tonnes.
- Further scale-up potential to meet market demands.

Specifications and Impurity Profile:

Specifications	Result
API Purity	Selective methods were chosen to control potential impurities, process-related impurities, and degradants (Purity > 99.5 %).
Chiral purity	>99.9 %
Genotoxic Impurities	API prepared as per Dr. Reddy's manufacturing process is free from possible GTI impurities. Control of all identified impurities below 0.15 %.
Nitrosamine Impurities	As per our complete chemistry assessment of the synthesis route for KSM, intermediates, reagents, and solvents, there is no possibility of N-Nitrosodimethylamine (NDMA) impurity formation at any stage in the synthesis.
Elemental impurities	< ICH Q3D
Particle size distribution (PSD)	Controlled crystallization to deliver consistent particle size distribution (PSD) Apremilast is a BCS Class IV drug and therefore requires a very fine PSD of the API to match the dissolution profile. We meet this requirement with the offering of a micronized API with customized particle sizes.
Retest period	48 Months
Storage conditions	Room temperature (25 °C) with excursion between 15 °C and 30 °C

IP & Regulatory:

- DMF's filed – US, Canada & Brazil.
- Favorable IP with NI Process for intermediates, API & Form-B.
- Successfully formulated into drug products with bioequivalence studies and approved in 10+ regions.

Region Specific Suitability:

- The API is suitable for global formulation development.
- Zone IVB stability and AMV as per RDC 166 will be available to meet the regulatory requirements for Brazil.
- No use of solvent mixtures in crystallization steps, making the product suitable for Brazil
- Five chemical conversions in the process make the product suitable for China, and Japan.

Sustainable Supply Chain:

- A fully backward integrated process with all intermediates being manufactured either at our in-house facilities or strategic manufacturing partners.
- Credible dual sources for key starting materials.

Proven Track Record in Drug Product Development:

- Successful formulation development, BE studies, and dossier filing with Dr. Reddy's API by several external customers across markets, including but not limited to Europe, Turkey, and MENA.

Beyond APIs – One Supplier for the API and Drug Formulation:

With full regulatory support, we can also provide you with the finished formulations for select markets. After approval, we can supply finished formulations in primary and secondary packaging or support the tech transfer to your manufacturing site.

- Besides the traditional strengths of 30 mg, we also offer 10 or 20 mg.
- Having one source for the API and the formulation can provide a more robust supply.
- Decreases the complexity and shrinks timelines for customers, compared to internal development and manufacturing.
- Access to ready-made dossiers along with complete regulatory support/guidance for registration.
- Option of both bottle and blister packs for 30 mg strength.
- Availability of all three strengths (10 mg, 20 mg, and 30 mg) in starter blister packs.

Scan this QR Code to contact us:

Scan this QR code and follow our API channel on LinkedIn:

For more information or to order sample quantities of APIs or formulations, log in to our customer service portal **XCEED** (**https://api.drreddys.com/customer_portal/login**) (or) contact us at **api@drreddys.com**.

Note: *Products under patent(s) are offered only for R&D purposes U/S 107A of the patent act and not for commercial sale