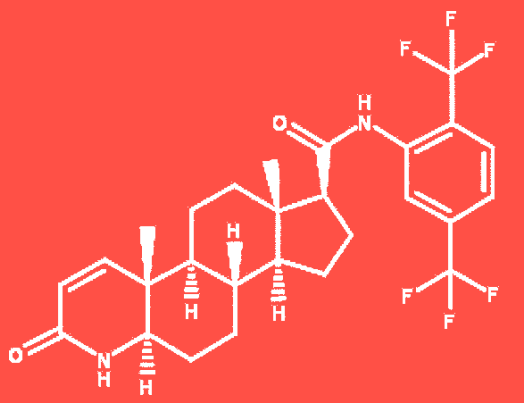
Dutasteride



Dutasteride API

Chemical Name: N-[2,5-bis(trifluoromethyl)phenyl]-3-oxo-4-aza-5α-androst-1-ene-17β-carboxamide

Chemical Formula: $C_{27}H_{30}F_6N_2O_2$

Dutasteride is indicated for treating symptomatic benign prostatic hyperplasia (BPH). When combined with the alpha-adrenergic antagonist, tamsulosin is indicated for treating symptomatic BPH in men with an enlarged prostate [1]. Furthermore, Dutasteride is also approved for treating male androgenic alopecia in South Korea and Japan at a dose of 0.5mg/ day [2].

Approval Date	Approved Indication
July 14, 2010	FDA approved Dutasteride (Jalyn®), a fixed-dose combination of dutasteride and tamsulosin, for symptomatic BPH in men with an enlarged prostate [2].
December 1, 2002	FDA approved Dutasteride (Avodart®) to treat the symptoms of an enlarged prostate (benign prostatic hyperplasia-BPH) [3].

Market Overview

Dutasteride has $945Mn sales globally, with 1050 kg of API demand and a Year-over-year (YoY) growth of 6% v/v. The National Institutes of Health (NIH) reports that benign prostatic hyperplasia affects around 50% of men between 51 and 60 years of age and 90% of men older than 80 [4]. Globally, the aging male population is driving the demand for Benign Prostatic Hypertrophy (BPH) drugs, as the condition is particularly prevalent in men over 50.

Dr. Reddy's API Offering

- We offer polymorphic crystalline form 2.
- A novel synthetic process developed for crystalline form 2.
- Quality by design (QBD) based API development for a consistent quality profile.

Specifications and Impurity Profile

Specifications	Result	
API Assay	• API has a comprehensive impurity profile in accordance with ICH Q3A guidelines and as per USP monograph. • The API specification for assay by HPLC limit is defined as not more than (NMT) 97.0% - 102%.	
API Impurity Profile	Limit of specified impurities are defiend as per USP: Method-1 I. Isomer II. Des methyl Dutasteride III. Any other impurity Method-2 I. Dutasteride acid (DAT-1) II. Dutasteride dimethylamide III. Dutasteride methyl ester IV. Dutasteride ethyl ester V. Dutasteride 17α-5-ene VI. Dutasteride 17α-epimer VII. Chlorodutasteride VIII. Dutasteride 5-ene IX. Any other individual impurity Method-3 I. Dihydrodutasteride II. Dutasteride α-dimer III. Dutasteride β-dimer IV. Any other individual impurity V. Total impurities(M-I+M-II+ M-III)	 NMT 0.15% NMT 0.15% NMT 0.10% NMT 0.2% NMT 0.2% NMT 0.15% NMT 0.2% NMT 0.2% NMT 0.3% NMT 0.4% NMT 0.3% NMT 0.1% NMT 0.15% NMT 0.3% NMT 0.5% NMT 0.1% NMT 2.0%
Genotoxic Impurities	As per the GTI assessment report of Dutasteride threshold of toxicological concern (TTC) limit is: [Concentration limit]/(ppm) = 3000 ppm (0.3%).	
Nitrosamine Impurities	Nitrosamine impurities risk assessment has been performed. Based on the assessment report N-nitrosodimethylamine (NDMA) content by GCMS with a limit of NMT 3.0 ppm (in-house) is being monitored.	
Elemental Impurities	< ICH Q3D.	
Particle size distribution (PSD)	Dr. Reddy's API offers particle sizes conducive to formulators, has demonstrated success in bio studies through various partners in key markets, and provides PSD per customer requirements.	
Retest period / Stability data	• Retest period of 5 years. • As per Dr. Reddy's USDMF specification, store at a control room temperature of 20 to 25°C (Excursions allowed between 15°C and 30°C).	

DMF filings and regulatory support

- Dr. Reddy's is among the earliest generic API manufacturers globally to file the USDMF for Dutasteride API form 2 and has DMFs filed in all major markets - Canada, Europe, Japan, Korea, Taiwan, China, Russia, Singapore, Switzerland, Brazil, and Saudi Arabia.
- Our customers have received regulatory approvals in the US, Canada, Saudi Arabia, Australia, Russia, China, South Africa, and Turkey.

Manufacturing and Supply Assurance

- We manufacture Dutasteride API at our cGMP manufacturing facility, which was successfully inspected by international regulatory authorities - USFDA, WHO GMP, KFDA, PMDA, Health Canada, and ANVISA.
- We have reliable KSM suppliers to ensure timely deliveries and adhere to stringent specifications.
- API and drug product is manufactured in a controlled facility designed to handle steroidal molecules.
- We are multi-sourced on our KSMs to provide supply assurance.

Batch size	Capacity
Current batch size of Dutasteride is 6.00 kg input of DUT-4 and expected output yied is 4.82 – 5.82 kg (80.33% -97.00%)	Adequate capacity available to supply development quantity in a short lead time.

Sustainability

- Continuous improvement - to achieve sustainability, quality, and supply excellence.
- Our API manufacturing plant is a zero-liquid discharge facility, which means that all the liquid waste and effluent they generate is treated within their premises and reused.
- We also co-processed/recycled 91% of our total hazardous waste and continue to be on course to meet our target of zero hazardous waste.

Scan this QR Code to contact us:

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References:

1. https://api.drreddys.com/product/dutasteride
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4969473/
3. https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021319s015lbl.pdf
4. https://www.businesswire.com/

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.**

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