

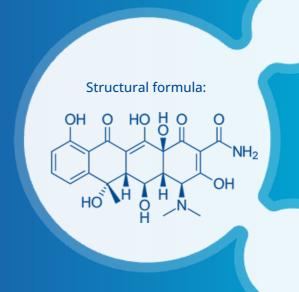
OXITETRACYCLINE CALCIUM

Product Type: Tetracycline Antibiotic

CAS Number: 15251-48-6

Common Indications: pneumonia and other infections of the respiratory tract. Also in the treatment of Acne and Rosacea.

Product Status: Project under development.



Our API Oxytetracycline calcium is manufactured in accordance with cGMP and stringent international quality standards. Our quality control follows every stage from development of analytical methods to the control of manufacturing process.

Oxytetracycline calcium is an antibiotic belonging to the tetracycline class that potently inhibits Gram-negative and Gram-positive bacteria, including some species of mycoplasmas and rickettsiae. This molecule is a protein synthesis inhibitor and prevents the binding from aminoacil-tRNA to the complex m-ribosomal RNA. Also possesses anti-HSV-1 activity.



CHARACTERISTICS AND THERAPEUTIC USE AS A DRUG

Oxytetracycline Calcium is the calcium salt of Oxytetracycline, a substance produced by the growth of certain strains of Streptomyces rimosus or obtained by any other means. It is also a **Tetracycline derivative** with actions and uses like those of tetracycline. On the other hand, the antimicrobial action is like Tetracycline hydrochloride, but somewhat less active against many organisms.



FINISHED DOSAGE FORMS

Oxytetracycline and its salts have been applied topically, often in combinations with other agents, as a variety of eye and ear drops, syrup, ointments, creams and sprays.





EFFICACY:

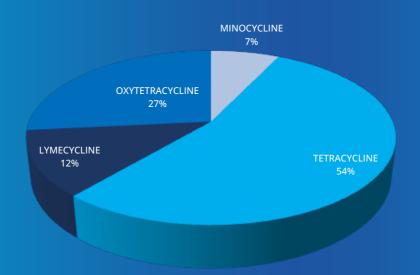
- Tetracycline derivative with similar action and indications.
- Bacteriostatic action over a wide range of bacteria.
- Good safety profile and is generally well tolerated.

SAFETY:

• It presents well and completely absorption.



MARKET STATUS



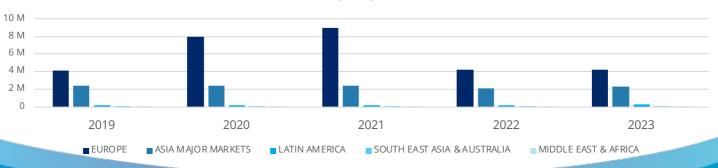




API CONSUMPTION (kg)



SALES FDF (USD) 2022-2023





KEY POINTS:

- Global consumption of 120 MT.
- Well established market.
- 7 M USD global market sales in 2023.

OXITETRACYCLINE CALCIUM PATENT PROTECTION OFF

DOCUMENTATION:

- CoA available
- MSDS available

Other information:

- Self life: 24 months
- Storage conditions: The storage of Oxytetracycline Calcium must be made in airtight containers at a temperature below 8 °C.
- Container clousure system: Bag 40 g. Polyethylene bag inside another polyethylene bag both heat-sealed. The bags are stored in a cardboard drum with a plastic lid.
- Samples available

Supply:

 We have a long lasting strategic commitment with our products that ensures continuity an security of supply





CONTRACT MANUFACTURER:

Cipan, our facility located in Portugal with more than 75 years of experience in the API synthesis business (Chemical and Fermentation).

CIPAN started its activity in 1963. The plant site is located in Castanheira do Ribatejo, approximately 40 kilometers North of Lisbon. Since 2016, CIPAN is a company of the SUANFARMA Group.

Cipan develops and manufactures products in accordance with cGMP and stringent international quality standards.

Cipan's standards are regularly verified through audits conducted by clients and international authorities.

• Relevant Certifications: EU and FDA GMPs, ISO 14001: 2015.

Relevant Information:

- Own european facility: CIPAN. Portuguese facility with over 50 years of API fermentation and organic synthesis expertise.
- · EU-GMP certificate.
- FDA certificate.
- Plant successfully audited by European and American customers.
- CEP for other products available.
- · Competitive price.
- · Large scales API organic semi-synthesis units.
- Installed fermentation capacity in excess of 850.000 liters.



MORE INFORMATION

FOR MORE INFORMATION PLEASE CONTACT:

NARCIS BRUGADA (humanapis@suanfarma.com)

HUMAN API BUSINESS UNIT DIRECTOR