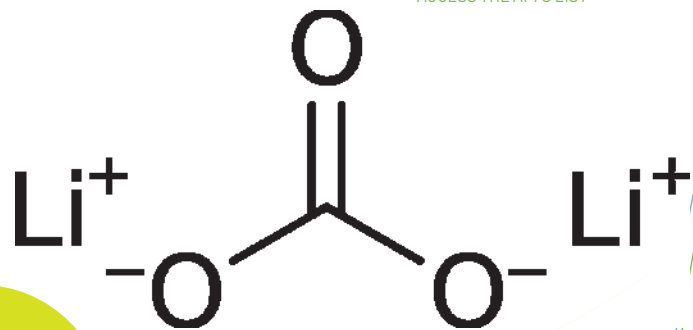


# LITHIUM CARBONATE

CAS# 554-13-2



ACCESS THE API'S LIST



**CHEMICAL STRUCTURE**

## THERAPEUTIC CLASS:

Lithium carbonate is an API which acts in the central nervous system and it is employed in drug products for the depression and bipolar disorder treatment.

## 3.2.S.4.1. SPECIFICATION

Presents the specification to be used to approve Lithium carbonate

### TEST PARAMETER AND SPECIFICATION OF LITHIUM CARBONATE

Test		Specification	References	
			Specification	Methodology
Appearance		White powder	In-house	In-house
Identification	A - Carbonate	Positive	USP NF	USP NF
	B - Lithium	Positive	In-house	In-house
Loss on drying		Not more than 1.0%	USP NF	USP NF
Impurities	Chloride	Not more than 0.07%	USP NF	USP NF
	Sulfate	Not more than 0.1%		
	Aluminum and Iron	No turbidity or precipitate is observed	In-house	In-house
	Calcium	Not more than 0.15%	In-house	In-house
	Sodium	Not more than 0.1%	In-house	In-house
Assay (Anhydrous Base) (%) - Dried basis		Not less than 99.0%	In-house	In-house
Granulometry (% retained at 200 mesh)		Not more than 30%	In-house	In-house

Note: Products protected by valid patents are not offered for sale in countries where the sale of such product constitutes patent infringement. Liability for patent infringement is solely understood at the risk of the purchaser.

**12 reactors**  
FOR  
MANUFACTURING

**31,500**  
LITERS OF  
REACTION  
PER DAY

INVESTMENTS  
THAT GUARANTEED  
**RESULTS**

**12**  
CLEAN  
ROOMS

**CHEMICAL  
FORMULA:**

Li<sub>2</sub>CO<sub>3</sub>



**REFERENCE  
DRUG PRODUCT:**

Carbolitium  
(Eurofarma Laboratórios)



**POLYMORPHISM:**

No polymorphism



**STATUS:**

DMF Available (USP-NF and in-house method) – The API is packed every 20kg in a double low density polyethylene bags, sealed with clamps seal and stored into a Kraft fiber barrel at room temperature (15 to 30 °C) with a shelf life of 48 months.

DMF Under development - Available in 2022 (EP and in-house method).



**MONTH  
PRODUCTION  
OF UP TO:**

15 ton



**API  
UNIT**

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**MORUMBI  
OFFICE**

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**PHARMACEUTICAL  
UNIT**

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DEVELOPMENT**

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