



# Food & Drugs Control Administration

BLOCK NO. 8, 1<sup>ST</sup> FLOOR, DR. JIVRAJ MEHTABHAVAN,  
GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010



Certificate No. : **1706204**

On the basis of the inspection carried out on **30-31/01/2017 & 12/05/2017** we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1 Name & Address of site : **AMOLI ORGANICS PVT. LTD..**

**BLOCK NO. 422, ECP CANAL ROAD,, VILLAGE- LUNA, Tal - PADRA**

**City : LUNA - 391 440, Dist : VADODARA,**

**GUJARAT STATE, INDIA**

2 Manufacturer's Licence number : **G/25/1518 G/28/1100**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
BULK DRUG (API) IP/ BP/ USP / EP / JP	General	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **22/06/2019**. It becomes invalid if the activities and /or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

**Format of this certificate is as per WHO TRS No. 908 of 2003.**

## Address of certifying authority

Food & Drugs Control Administration,  
Block No. 8, 1<sup>ST</sup> floor, Dr. Jivraj Mehta  
Bhavan, Gandhinagar, Gujarat State,  
India. - Pin : 382010

Email : [comfdca@gujarat.gov.in](mailto:comfdca@gujarat.gov.in)

Phone : 91-79-23253417, Fax : 91-79-232-53400

Date : **23/06/2017**

Name & function of : **(Dr.H.G.KOSHIA)**  
responsible Person **Commissioner**






**Drug Manufacturing License No. G/1100 & G/1518 in Form 26**  
**List of Product under WHO-GMP Certificate**

Sr. No.	Product Name	Pharmacopeia Status
1.	Aripiprazole	USP
2.	Ascorbic Acid	IP/EP/BP/USP
3.	Ascorbic Acid Coated	In-House
4.	Atorvastatin Calcium Trihydrate	IH/IP/EP/BP/USP
5.	Carbamazepine	IP/EP/BP/USP/JP
6.	Celecoxib	IH/EP/USP
7.	Chlorthalidone	IP/EP/USP
8.	Dihydralazine Mesylate	In-House
9.	Hydrochlorothiazide	EP/BP/USP
10.	Levetiracetam	EP/USP
11.	Linezolid	IH
12.	Olmesartan Medoxomil	IH/EP/USP
13.	Oxcarbazepine	IH/IP/EP/USP
14.	Rosuvastatin Calcium	IH/IP/ EP
15.	Sertraline Hydrochloride	IH/IP/EP/BP/USP
16.	Sildenafil Citrate	IH/EP/USP
17.	Sodium Ascorbate	IP/EP/BP/USP
18.	Tadalafil	EP/USP
19.	Telmisartan	EP/BP/USP
20.	Venlafaxine Hydrochloride	EP/BP/USP



For, Amoli Organics Pvt. Ltd., Vadodara

Nilesh Patel  
DGM – Quality Assurance  
Amoli Organics Pvt. Ltd.

  
For Commissioner  
Food & Drugs Control Administration  
Gujarat State, Gandhinagar

23 JUN 2017 TO 22 JUN 2019

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