

7-5/2013/EU/WC-0054
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 15 JUL 2019

To
M/s Ami Lifesciences Pvt Ltd.
Block No. 82/B, ECP Road,
At & Post Karakhadi, Tal -Padra,
City Karakhadi, Vadodara- 391 450,
Gujarat, India.

SUB: Written Confirmation of M/s Ami lifesciences Pvt Ltd., Block No. 82/B, ECP Road, At & Post Karakhadi, Tal Padra, City Karakhadi, Dist Vadodara- 391 450, Gujarat, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to CDSCO, Ahmedabad Zone and the recommendation received from DDC (I), Ahmedabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).
2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.
3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.
4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.
5. The Written Confirmation will be withdrawn in the events of non-compliance of Standards.
6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.



Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s Ami Lifesciences Pvt Ltd.
Block No. 82/B, ECP Road,
At & Post Karakhadi, Tal- Padra
City Karakhadi, Vadodara- 391 450,
Gujarat,India

List of APIs:

Sl.No	Name of the active substances	Activities
1.	Ambroxol Hydrochloride BP/EP	Manufacturing & Packing
2.	Betahistine Dihydrochloride USP/BP/EP	Manufacturing & Packing
3.	Flavoxate Hydrochloride BP/USP	Manufacturing & Packing
4.	Pamabrom USP	Manufacturing & Packing
5.	Rutoside Trihydrate Ph.Eur.	Manufacturing & Packing
6.	Tadalafil Ph.Eur./BP/USP	Manufacturing & Packing

ITEM(S) Six (06) ONLY

The Written Confirmation remains valid until: 26.06.2022


Signature

Stamp of the authority and date



15 JUL 2019

o/c
10-7-2019


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7. In the event of any Non-Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of issue	Validity
01	13	27.06.2019	26.06.2022
02	06	15 JUL 2019	26.06.2022

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

o/c
10.7.2019
11.7.19
11/07/19