



Australian Government

Department of Health
Therapeutic Goods Administration

Mr Mert Alver
Atabay Pharmaceutical Fine Chemicals Inc
Koftuncu Sokak No 1 Kadikoy
Acibadem Istanbul
Turkey

TGA Reference: E18-270706

Dear Mr Alver,

Subject: Issue of GMP certificate MI-2018-CE-03511-1

Please find enclosed the GMP certificate for your manufacturing premises.

The certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The inspection frequency is not a reflection of the expiry date shown on the certificate but is consistent with the re-inspection frequency applicable to Australian manufacturers of the same class of products.

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

Yours sincerely,

Signed and authorised by

Robert Prestridge
Senior Inspector
Manufacturing Quality Branch

10 May 2019

Contact: gmp@tga.gov.au, phone +61 2 6221 6881 or fax +61 2 6232 8426



Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2018-CE-03511-1

Issued to:

Atabay Pharmaceutical Fine Chemicals Inc

Manufacturing Site Address:

Koftuncu Sokak No 1 Kadikoy
Acibadem Istanbul Turkey

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer of Active Pharmaceutical Ingredients (APIs) has been inspected following section/s 25(1)(g), 26(1)(g) and/or 26A(3) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing API manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 17 to 18 October 2018, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 January 2017.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 18 April 2021

ISSUE DATE: 10 May 2019

This Certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.



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Certificate of GMP Compliance of a Manufacturer of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2018-CE-03511-1

MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of APIs as therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Active Pharmaceutical Ingredient manufacture	Non Sterile	API - Not Defined	Raw material	Milling
Active Pharmaceutical Ingredient manufacture	Non Sterile	API - Not Defined	Raw material	Testing chemical and physical
Active Pharmaceutical Ingredient manufacture	Non Sterile	API - Not Defined	Raw material	Testing microbial
Active Pharmaceutical Ingredient manufacture	Non Sterile	API - Not Defined	Raw material	Release for supply

The certificate is limited to the manufacture of APIs by chemical synthesis.

ACTIVE SUBSTANCES MANUFACTURED

Paracetamol

Paracetamol DC

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