Australian Government

Department of Health
Therapeutic Goods Administration

Mr Mert Alver
Atabay Pharmaceutical Fine Chemicals Inc
Atabay Kimya Sanayi ve Ticaret AS Dilovasi Organize Sanayi Bolgesi 4 Kisim Sakarya Caddesi No 28
Gebze Kocaeli 41400
Turkey

TGA Reference: E18-270706

Dear Mr Alver,

**Subject: Issue of GMP certificate MI-2017-CE-12255-1**

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-2017-CE-12255-1

**Issued to:**

Atabay Pharmaceutical Fine Chemicals Inc

**Manufacturing Site Address:**

Atabay Kimya Sanayi ve Ticaret AS Dilovasi Organize Sanayi Bolgesi 4 Kisim Sakarya Caddesi No 28
Gebze Kocaeli 41400 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 15 to 16 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**: **16 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.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health

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# Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

**Certificate Number:**

MI-2017-CE-12255-1

**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 | Active material manufacture |

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

**ACTIVE SUBSTANCES MANUFACTURED**

Paracetamol

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TGA Health Safety Regulation