



Medicines & Healthcare products
Regulatory Agency



MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

[gov.uk/mhra](https://www.gov.uk/mhra)

RESTRICTED – COMMERCIAL
Mr Rajiv Adukia
AV PROCESSORS PRIVATE LIMITED
E-52
ANAND NAGAR
MIDC
AMBERNATH (EAST)
THANE
MAHARASHTRA
IN-421 506
INDIA



Certificate No: UK GMP 36045 Insp GMP 36045/1296204-0005

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	AV PROCESSORS PRIVATE LIMITED
Site address	E-52 ANAND NAGAR MIDC AMBERNATH (EAST) THANE MAHARASHTRA IN-421 506 INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art.111(4) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 03/06/2019, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.



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Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

1.4.2 Sterilisation of active substances/excipients/finished product

1.4.2.5 Gamma irradiation

1.5 Packaging

Not Authorised

1.6 Quality control testing

Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised



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3. MANUFACTURING OPERATIONS

- 3.1 Manufacture of Active Substance by Chemical Synthesis**
Not Authorised

- 3.2 Processing Activities of Active Substance from Natural Sources**
Not Authorised

- 3.3 Manufacture of Active Substance using Biological Processes**
Not Authorised

- 3.4 Manufacture of sterile active substance**
Not Authorised

- 3.5 General Finishing Steps**
Not Authorised

- 3.6 Quality Control Testing**
Not Authorised

- 4 Other Activities**
Not Authorised



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Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

5. Medicinal Product(s)/IMP(s)

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

**Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk**

Date: 18/07/2019