



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.