

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	RUSAN PHARMA LIMITED
Site address	PLOT NO. 6406 GIDC ANKLESHWAR DISTRICT BHARUCH GUJARAT 393002 INDIA

Is an active substance manufacturer that has been inspected in accordance with Art. 80(1) of Directive 2001/82/EC* transposed in the following national legislation: The current Veterinary Medicines Regulations.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 24/10/2008, it is considered that it complies with the principles of GMP for active substances

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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.



Manufacture of active substance. Names of substances subject to inspection:

BUPRENORPHINE HYDROCHLORIDE.

(Manufacture of this API was inspected in relation to use in a veterinary product, but the API would be acceptable for use in human medicinal products.)



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

N/A

1. Building(s)/Area(s)

Manufacturing plant I plus associated warehouse, laboratory and utilities support areas.

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

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

BUPRENORPHINE HYDROCHLORIDE.

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

David Cunningham
GMP Inspector
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Date: 04/02/2009

