Safeguarding public health

Certificate No: UK API 35202 Insp GMP 35202/933211-0001

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	ZHEJIANG SUPOR PHARMACEUTICAL COMPANY LIMITED
Site address	YUEDONG ROAD PAOJIANG INDUSTRIAL ZONE SHAOXING ZHEJIANG RC-312071 CHINA

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 18/10/2010, 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.

Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road London SW1W 9SZ
T 0203 080 6000 www.mhra.gov.uk

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

ACTIVE NAME
QUETIAPINE FUMARATE
TINIDAZOLE

EXCIPIENT NAME
N/A