

CERTIFICATE. NO.:

WC-0123

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site:

M/s. Piramal Enterprises Limited,

Sy No. 7-70, 70/1 and 70/2, Digwal Village, Kohir Mandal,

Medak Dist. AP.

2. Manufacturer's licence number: 220/AP/MD/96/B & F/R dated 12/12/1996

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per List enclosed as Annexure-1

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU(= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant:

31th January to 02nd February, 2012 by USFDA.

The Written Confirmation remains valid until: 02nd July, 2016

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: Central Drugs Standard Control Organisation

FDA Bhawan, Kotla Road, New Delhi- 110 002, India

Name and function of responsible person: Dr. G.N. Singh,

Drugs Controller General (India)

E-mail:

Telephone no.:

Fax no.:

dci@nic.in,

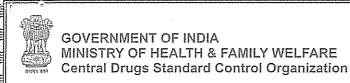
+91-11-23236965

+91-11-23236973

Signature

Stamp of the authority and date

131 JUL 7013



GERTIFICATE. NO.:

WC-0123

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC 1. Name and address of site:

M/s. Piramal Enterprises Limited

M/s. Piramal Enterprises Limited, Sy No. 7-70, 70/1 and 70/2. Digwal Village, Kohir Mandal. Medak Dist. AP.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Amiodarone HCl (Ph. Eur.)	Manufacturing & Packing
2.	Aprepitant (IH)	
3.	Brimonidine Tartrate (IH)	Manufacturing & Packing
4.	Diltiazem HCI (IP/BP/Ph. Eur./USP)	Manufacturing & Packing
5.		Manufacturing & Packing
}	Flecainide Acetate (Ph. Eur./USP)	Manufacturing & Packing
6.	Trazadone HCI (BP/USP)	Manufacturing & Packing
7.	Isoflurane (BP/Ph. Eur./USP)	Manufacturing & Packing
8.	Ketoconazole (IP/BP/Ph. Eur./USP)	Manufacturing & Packing
9.	Levobunolol HCI (BP/Ph. Eur./USP)	Manufacturing & Packing
10.	Mebeverine HCI (BP)	Manufacturing & Packing
11.	Memantine HCI (IH)	Manufacturing & Packing
12.	Oxybutynin HCI (IP/BP/USP)	Manufacturing & Packing
13.	Promethazine Teoclate (IP/BP/USP)	Manufacturing & Packing
14.	Sulindac (USP)	Manufacturing & Packing
15.	Tramadol HCI (IP/BP)	Manufacturing & Packing
16.	Verapamil HCl (IP/BP/Ph. Eur./USP)	
17.	Halothane (Bulk)	Manufacturing & Packing
	Traidthane (Dulk)	Manufacturing & Packing

ITEM(S) Seventeen (17) ONLY

The Written Confirmation remains valid until: 02nd July, 2016

Signature

Stamp of the authority and date

JUL 2013

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