



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: 31st 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.:

dcic@nic.in,

+91-11-23236965

+91-11-23236973

Signature

Stamp of the authority and date



131 JUL 2013



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1. Name and address of site: M/s. Piramal Enterprises Limited,
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Medak Dist. AP.

List of APIs:

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

ITEM(S) Seventeen (17) ONLY

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

Signature

Stamp of the authority and date



31 JUL 2013