File No.04-103/2001-DC
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
Nirman Bhawan, New Delhi - 110 011 (INDIA)

Form-46
(See rules 122-B and 122-D and 122-DA)
Permission / approval for manufacture of new drug formulation

Number of the permission and date of issue: MF-7089/06

A/s. Cipla Ltd., Mumbai Central, Mumbai-400 008. (Address)

Hereby granted permission/approval to manufacture the following new drug formulation under rule 122-D/422-D/122-DA of the Drugs and Cosmetics rules-1945, namely:

1) Name of the drug: Misoprostol Tablets.

2) Dosage Form: Tablet.

3) Composition: Each uncoated tablet contains:
Misoprostol: 250/100/200mcg.

4) Indication: For cervical ripening, prevention of post partum hemorrhage and first trimester abortion with mifepristone.

Date: 6 DEC 2006

Signature: ________________________________
(Dr. M. Venkateswarlu)
Drugs Controller General (India)
(Name & Designation of Licensing Authority)

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