

Office of The Commissioner,
Food & Drug Administration (M S)
2nd Floor, Survey No. 341,
Bandra - Kurla Complex,
Bandra (East), Mumbai - 400 051.

Date 3/9/2011.

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This certificate conforms to the format recommended by the **World Health Organization** (general instructions and explanatory notes attached)

Certificate No. WHO-Gmp/CERT/HQ-NEW-124-2011/1726/11.

On the basis of the inspection carried out on 11.08.2011 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name and address of site: **SMB Corporation of India,**
13, 33-36, Prem Industrial Estate, Subhash Road,
Jogeshwari (East), Mumbai - 400 060.

2. Manufacturers licence number : **In Form. 28 No. 99**

3. Table 1:

Sr. No	Pharmaceutical Product	Category (ies)	Activity (ies)
1.	Intra Uterine Contraceptive Devices (As per Annexure)	Devices	Molding, Assembling, Packing and Quality Control
2.	Non Absorbable Surgical Needled Sutures (As per Annexure)	Suture	Assembling, Packing and Quality Control

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains Valid until **1 SEP 2013** It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.



Name of the authorized person : O.S. Sadhwani
Signature:

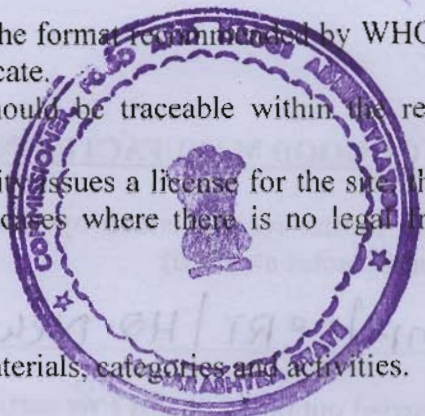
Stamp & Date :

Joint Commissioner (Law)
Food and Drug Administration
Maharashtra State, Bandra(E)
Mumbai, INDIA

- 2 SEP 2011

Explanatory notes:

1. This certificate, which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a license for the site, this number should be specified. Record "not applicable" in cases where there is no legal framework for the issuing of a license.
4. Table 1



List of dosage forms, starting materials, categories and activities. Examples are given below.

Example 1

<i>Pharmaceutical Product(s)</i>	<i>Category (ies)</i>	<i>Activity (ies)</i>
<i>Dosage form (s):</i>		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, quality control
	Penicillin	Repackaging and labelling
Injectables	Cefalosporin	Aseptic preparation, packaging, labelling

Example 2

<i>Pharmaceutical Product(s)</i>	<i>Category (ies)</i>	<i>Activity (ies)</i>
<i>Starting material (s)</i>		
Paracetamol	Analgesic	Synthesis, purification, packing, labelling

Use, whenever available, International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

(5) The certificate remains valid until the specified date. The certificate becomes invalid if the activities and / or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

(6) The requirements for good practices the manufacture and quality control of drugs referred to in the Certificate are those included in Quality Assurance of Pharmaceuticals a compendium of guidelines and related materials, Good Manufacturing practices and inspection, volume 1, 1999 World Health Organization, Geneva and subsequent updates.



Valid upto: **1 SEP 2013**

ANNEXURE

Certificate No. : **WHO-Gmp /CERT /HQ-NEW -124-2011.**

Name and address of the firm : **SMB Corporation of India,
13, 33-36, Prem Industrial Estate,
Subhash Road, Jogeshwari (East),
Mumbai - 400 060.**

Licence No. : **In Form 28 No. 99 .**



List of products approved for COPP

1. Intra Uterine Contraceptive Device

- (1) Sterile Copper T 380A Intrauterine Contraceptive Device (IUD-TAMBI)
- (2) Sterile SMB Cu 375 Standard Intrauterine Contraceptive Device
- (3) Sterile Copper T 200B Intrauterine Contraceptive Device (IUD-TAMBI)

2. Non Absorbable Surgical Needled Sutures

- (1) Sterile Polyamide Monofilament Needled Suture BP/USP.
- (2) Sterile Braided Silk Needled Suture BP/USP.
- (3) Sterile Braided Polyester Needled Suture BP/USP.
- (4) Sterile Polypropylene Monofilament Needle Suture USP

Name of the authorized person: O.S. Sadhwani

Signature:

Stamp and Date:

Joint Commissioner (Law)
Food and Drug Administration
Maharashtra State, Bandra
Mumbai, INDIA

2 SEP 2011