



Office of The Commissioner,  
Food & Drugs Administration M.S.  
Bandra – Kurla Complex,  
Bandra (E),  
Mumbai – 400 051  
Date : 05/10/2016

**NOTARIAL REG**

ENTRY No. 2903  
DATE 24/10/16

# **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/ND/50642/2016/11/16820

On the basis of the inspection carried out on 26-02-2014 AND 27-02-2014, 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.

- Name of the Firm : NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD.  
Address : PLOT NO. 85, WANJARA LAY-OUT, PILI NADI  
INDL. AREA, KAMPTEE ROAD NAGPUR  
NAGPUR 440026 MAHARASHTRA STATE,  
INDIA
- Licence No. : ND15 In Form 25

Table 1

| Sr.No. | Dosage Form(s)                                  | Categor(ies)                                                           | Activity(ies)                                                                   |
|--------|-------------------------------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| 1      | Active Pharmaceutical Ingredients ( Bulk Drugs) | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance |

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

The Certificate was valid upto 01 Apr 2016. and the validity of the said certificate was extended for the period of six months and the certificate was valid upto 01 Oct 2016. Now the validity of this certificate has been further extended for the period of six months and now the validity of this Certificate remains 01 Apr 2017. 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.

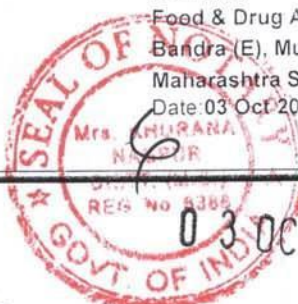
Address of certifying authority :  
Food & Drug Administration  
Bandra-kurla Complex  
Bandra (E), Mumbai – 400 051  
Maharashtra INDIA  
Tel : +91-22-26592366  
Fax : +91-22-26591199

Name of the Authorised person : O S SADHWANI

Signature

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.  
Bandra (E), Mumbai  
Maharashtra State, India  
Date: 03 Oct 2016



**ATTESTED**

Advocate & Notary

H/No 410/3, Meehan Road, Nagpur



Attested  
For Nag. Vidarbha Chamber of Commerce

Sanjay K. Agrawal  
Hon. Jt. Secretary

CONSULADO DE CHILE EN  
NUEVA DELHI, INDIA

El Cónsul de Chile que suscribe certifica la  
autenticidad de la firma de don.....*Pushpa Ranjan*  
funcionario para asuntos consulares del Ministerio  
de Relaciones Exteriores de India.

Actuación No.....*4598*.....Arancel Art No. 4/10

Derechos percibidos: US \$.....*12*.....

NUEVA DELHI.....*02*.....de.....*May*.....de.....*2016*



*GUSTAVO A. CANTUARIAS CONCHA*  
Cónsul de Chile

DERECHOS PAGADOS.....*12*.....  
COMPROB.DE PAGO No.....*1*.....  
ACT. No.....*4598*.....ART.....*4*.....No.....*10*



COUNTRY OF INDIA

**This public document of the type  
COMMERCIAL DOCUMENT**

is issued to  
PVT. LTD.

has been signed by

भारत सरकार GOVERNMENT OF INDIA  
अपोस्टिल / APOSTILLE  
(Convention de La Haye du 5 octobre 1961)  
INDIA

NITIKA PHARMACEUTICAL SPECIALITIES

SANJAY K AGRAWAL

with the seal / stamp of  
HON. JT. SECRETARY, NAG VIDARBHA  
CHAMBER OF COMMERCE, NAGPUR

**Certified by**  
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS  
on 28-Oct-2016 at NEW DELHI, INDIA

with reference no. MHNG0038463516

Seal / Stamp



Signature  
(*Pushpa Ranjan*)  
(PUSHPA RANJAN)  
अनुमति अधिकारी (अटलेशन)  
Section Officer (Attestation)  
सी.पी.डी. प्रभाग/CPV Division  
विदेश मंत्रालय, नई दिल्ली  
Ministry of External Affairs  
New Delhi



**INWARD**  
No. - 2704  
Date - 9/11/2016  
Sign. - *Parmole*

### 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 licence for the site, this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.
4. Table 1  
List the dosage forms, starting materials, categories and activities. Examples are given below.

#### Example -1

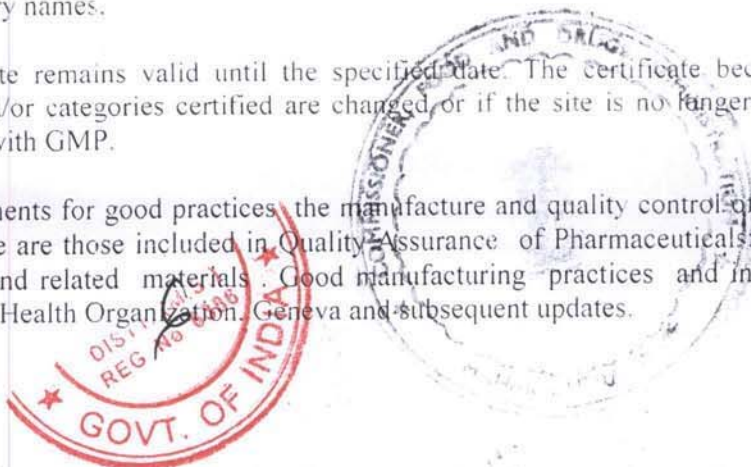
| Pharmaceutical Product (s)1 | Category (ies) | Activity (ies)                             |
|-----------------------------|----------------|--------------------------------------------|
| Dosage form (s)             |                |                                            |
| Tablets                     | Cytotoxic      | Packaging                                  |
|                             | Hormone        | Production, Packaging, Quality control.    |
| Injectables                 | Penicillin     | Repackaging & Labelling.                   |
|                             | Cefalosporin   | Aseptic preparation, Packaging, Labelling. |

#### Example - 2.

| Pharmaceutical Product (s)1 | Category (ies) | Activity (ies)                               |
|-----------------------------|----------------|----------------------------------------------|
| Starting material (s)2      |                |                                              |
| Paracetamol                 | Analgesic      | Synthesis, Purification, Packing, Labelling. |

Use, whenever available, International Nonproprietary Names (INNs) or otherwise rational 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 2, 1999, World Health Organization, Geneva and subsequent updates.



# LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>

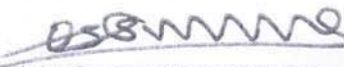
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 PLOT NO. 85, WANJARA LAY-OUT, PILI NADI  
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 NAGPUR 440026 MAHARASHTRA STATE, INDIA  
 Drug License No : ND15 In Form 25

| Sr.No.  | Name of the Product            | Composition |
|---------|--------------------------------|-------------|
| 1       | Aluminum Hydroxide Gel USP     |             |
| 2       | Aluminum Monostearate USP      |             |
| 3       | Calcium Carbonate USP          |             |
| 4       | Calcium Citrate USP/NF         |             |
| 5       | Calcium Glycerophosphate BP/EP |             |
| 6       | Calcium Stearate BP            |             |
| 7       | Calcium Stearate USP           |             |
| 8       | Dried Aluminium Hydroxide BP   |             |
| 1 2 3 4 |                                |             |



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 Bandra (E), Mumba - 400 051  
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 Fax: +91-22-26591959

Name of the Authorised person : O S SADHWANI

Signature   
 Stamp and Date: Joint Commissioner (HQ) & Controlling Authority  
 Food & Drug Administration, M.S.  
 Bandra (E), Mumbai  
 Maharashtra State, India  
 Date: 03 Oct 2016



03 OCT 2016

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| Sr.No.  | Name of the Product           | Composition |
|---------|-------------------------------|-------------|
| 9       | Dried Ferrous Sulfate USP     |             |
| 10      | Ferrous Fumarate USP          |             |
| 11      | Magaldrate USP                |             |
| 12      | Magnesium Glycerophosphate EP |             |
| 13      | Magnesium Hydroxide BP        |             |
| 14      | Magnesium Hydroxide Paste USP |             |
| 15      | Polyethylene Glycol USP       |             |
| 16      | Simethicon Emulsion USP       |             |
| 1 2 3 4 |                               |             |



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| Sr.No.  | Name of the Product                             | Composition |
|---------|-------------------------------------------------|-------------|
| 17      | Simethicone USP                                 |             |
| 18      | Sodium Stearyl Fumarate USP                     |             |
| 19      | Sucralfate USP                                  |             |
| 20      | Zinc Stearate EP                                |             |
| 21      | ACILUBE<br>Stearic Acid USP                     |             |
| 22      | CAPSEEDS<br>Sugar Sphere USP                    |             |
| 23      | Cellacefate<br>Cellulose Acetate Pthalate BP/EP |             |
| 24      | Magnesium Carbonate USP                         |             |
| 1 2 3 4 |                                                 |             |



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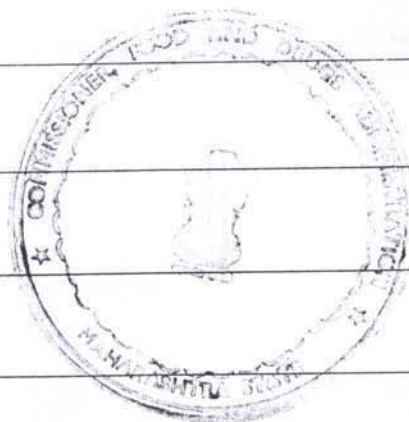
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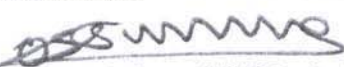
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| Sr.No. | Name of the Product                        | Composition |
|--------|--------------------------------------------|-------------|
| 25     | Magnesium Oxide USP                        |             |
| 26     | NEUTRA Almagate BP                         |             |
| 27     | STANPURE<br>CALAMINE BP                    |             |
| 28     | TABFIL D<br>Dibasic Calcium Phosphate USP  |             |
| 29     | TABFIL T<br>Tribasic Calcium Phosphate USP |             |
| 30     | TABGLIDE<br>Talc EP                        |             |
| 31     | TABLUBE<br>Magnesium Stearate USP          |             |



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