FDA MAHARASHTRA

NOTARY MRS. CHANCHAL KHURANA NAGPUR DIST. (M.S.) INDIA Regn. No. 6386 GOVT. OF INDIA

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.

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**
2. 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.

NOTARIAL ... CANCELLED

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai –
Maharashtra INDIA
Tel +91-22-2659236
Fax +91-22-2659

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
24/10/16
Advocate & Notary
H/No 410/3

SEAL OF NOTARY Mrs. CHURANA REG No 6386 GOVT. OF IND

03 OCT 2016

NAG VIDARBHA CHAMBER OF COMMERCE 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 Pushya 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

EMBAJADA DE CHILE EN INDIA
SECCION CONSULAR

GUSTAVO A. CANTUARIAS CONCHA
Cónsul de Chile

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

SERVICIO CONSULAR
2016
DE CHILE EN
USS - CHILE - USS
SERVICIO CONSULAR
SECCION CONSULAR
2016
2 2
USS - CHILE - USS

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

The Ministry of External Affairs accepts no responsibility for the contents of the above documents.

This public document of the type
COMMERCIAL DOCUMENT
is issued to NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD.
has been signed by 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
विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS
भारत सरकार, नई दिल्ली GOVT. OF INDIA, NEW DELHI
M05683

Signature
(पुष्पा रंजन)
(PUSHPA RANJAN)
अनुभाग अधिकारी (अत्यापन)
Section Officer (Attestation)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

SEAL OF NOTARY
MRS. KHURANA
NAGPUR

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

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 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 in 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.

GOVT. OF INDIA

VIDARBHA CHAMBER OF COMMERCE NAGPUR

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : WHO-GMP/CERT/ND/50642/2016/11/16820 VALID UP TO :01 Apr 2017

Name of Manufactring Firm : NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD. PLOT NO. 85, WANJARA LAY-OUT, PILI NADI INDL. AREA, KAMPTEE ROAD NAGPUR 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		

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Address of certifying authority
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumba - 400 051
Maharashtra INDIA
Tel +91-22-26592363/64
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

0 3 OCT 2016

VIDARBHA CHAMBER OF COMMERCE NAGPUR

GOVT. OF INDIA

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : WHO-GMP/CERT/ND/50642/2016/11/16820 VALID UP TO :01 Apr 2017

Name of Manufactring Firm : NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD. PLOT NO. 85, WANJARA LAY-OUT, PILI NADI INDL. AREA, KAMPTEE ROAD NAGPUR NAGPUR 440026 MAHARASHTRA STATE, INDIA

Drug License No : ND15 In Form 25

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		

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/64
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

M.S. KHURANA & CO. NAGPUR DIST. (M.S.) REG. No 6386 GOVT. OF INDIA

0 : 0 : 2016

VIDARBHA CHAMBER OF COMMERCE NAGPUR

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : WHO-GMP/CERT/ND/50642/2016/11/16820 VALID UP TO :01 Apr 2017

Name of Manufactring Firm : NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD. PLOT NO. 85, WANJARA LAY-OUT, PILI NADI INDL. AREA, KAMPTEE ROAD NAGPUR NAGPUR 440026 MAHARASHTRA STATE, INDIA

Drug License No : ND15 In Form 25

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

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Address of certifying authority
Food & Drug Administration, M.S
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra INDIA
Tel: +91-22-26592363/64
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

VIDARBHA CHAMBER OF COMMERCE NAGPUR

REG NO. 386 GOVT. OF INDIA

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : WHO-GMP/CERT/ND/50642/2016/11/16820 VALID UP TO :01 Apr 2017

Name of Manufactring Firm : NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD.
PLOT NO. 85, WANJARA LAY-OUT, PILI NADI
INDL. AREA, KAMPTEE ROAD NAGPUR
NAGPUR 440026 MAHARASHTRA STATE, INDIA

Drug License No : ND15 In Form 25

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

1 2 3 4

Address of certifying authority
Food & Drug Administration M.S.
Bandra-kurla Complex
Bandra (E), Mumbai – 400 051
Maharashtra INDIA
Tel +91-22-26592363/64
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

VIDARBHA CHAMBER OF COMMERCE NAGPUR

REG NO 6386 GOVT. OF INDIA