

DRUGS CONTROL ORGANISATION, SAANSIDHA BHANGAN, TILAK MARG,
JAIPUR.

No.DC/RHOGMP/2001/ 136

Dated 12/2/2001.

TO WHOM IT MAY CONCERN

Certified that M/s.Sunil Synchem Ltd., Alwar are holding valid licence bearing No.867 on Form No.25 issued on dated 8.12.81 to manufacture following category of drugs :-
1.Empty Hard Gelatin Capsule I.P.

As per inspection carried out of the said firm for the issue of WHO GMP Certificate on 3-4th Feb. 2000 based on this the WHO GMP Certificate is issued to the firm having validity of licence i.e.31.12.2006.

This certificate is not any way provide immunity from penal provision so far as matters arising out of provisions of Drugs and Cosmetics Act and Rules made there under are concerned and is likely to be cancelled at any time during the validity period if it is found that the firm is not observing mandatory requirements.



Drugs Controller
Rajasthan, Jaipur.

M/s.Sunil Synchem Ltd.,
17/18, Old Industrial Area,
Alwar.

Copy to :-

- 1.World Health Organisation, Indraprastha Estate, New Delhi.
- 2.Joint Drugs Controller (India), North Zone, Ghaziabad.
- 3.Asstt. Drugs Controller, Alwar Hqr. Jaipur.

Drugs Controller
Rajasthan, Jaipur



CERTIFICATE OF A PHARMACEUTICALS PRODUCT

INDIA
AFRICA
RUSSIA
SYRIA, USA
KOREA

Exporting (Marketing) Country :
Importing (Requesting) Country :

Proprietary name (if applicable) and dosage form :
Active ingredient(s) and amount(s) per unit dose :

Empty Hard Gelatin Capsules.

1. Is this product licenced to be placed on the market for use in exporting country? If yes, complete box A, if no complete box B.

A	
Product Licence holder	Sunil Synchem Ltd. Plot no. 17-18 Old Industrial Area Alwar (Rajasthan) 301 001
Status of Licence holder	a <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/> d <input type="checkbox"/>
Number of product license & date of issue	08.12.1981 : 867 dt.
Is an technical summary appended	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
is the attached technical product information complete & consonant with the licence ?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Applicant for certificate if different from the Licence holder	Not provided <input type="checkbox"/>
: Not Applicable	

B	
Applicant for certification	Sunil Synchem Ltd. Plot no. 17-18 Old Industrial Area Alwar (Rajasthan) 301 001
Status of Applicant	a <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/> d <input type="checkbox"/>
Why is authorization lacking?	not required <input type="checkbox"/> not required <input type="checkbox"/> not consideration <input type="checkbox"/> refuse <input type="checkbox"/>
REMARKS	

2. Does the certifying authority arrange for periodic inspection of the manufacturing plant which the 3 dosage form is produced ? Yes No if no proceed to question 3

Periodicity of routine inspection Twice in a year.

Has the manufacture of this type of dosage form been inspected Yes No

Do the facilities & operations conform to GMP as recommended by World Health Organisation Yes No

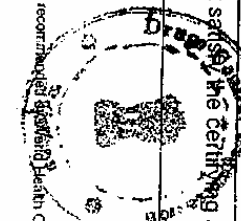
3. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the of the product ? Yes No if no explain:

Address of certifying authority _____

Telephone/Fax no : (0141) 381670

Validity up to : 31.12.2006

This certificate conform to the format recommended by World Health Organisation (General Instruction & explanatory note overleaf)



Name of the authorised person _____
Signature _____
Stamp & date ? **FCI 9991**

(P. N. SARASWATI)
Licensing Authority,
Drugs Controller,
Raj. JAIPUR