



Innovation
for a Better Life



COMPANY OVERVIEW

Agro Cool India Ltd is one of the leading manufacturers of API's situated in the Northern part of India. The manufacturing site compasses area of 7526 sq mtrs, the cover area being 3650 sq mtrs which consist of Main Plant, Admin Office, Raw Material Store, Finish Product Stores, Quality Control Lab, Microbiological Lab, R & D Lab, Quality Assurance, Purified Water Plant, ETP and Utilities.

We are into Chemical Manufacturing Business under Jain Group of Industries since 1979 with manufacturing of Plasticizer & Dyes Chemicals having two units in Gujarat, India. The foundation of Agro Cool India Ltd was laid down in the year 2004 for manufacturing of bulk drugs. Thereafter in year 2006 we commenced our production with Vitamin B3 i.e. Niacinamide & Niacin. In year 2013, we started with the production of Corticosteroids in a separate auditable GMP facility.

Since our inception, we have gained a reliable and cost-competitive advantage with certifications such as GMP by FDA, WHO GMP, ISO 9001:2015, HACCP, KOSHER, HALAL & GLP.

VISION

We shall become the first choice vendor of bulk drugs and achieve a leadership position by

- Assuring consistent quality & timely delivery at competitive prices.
- Providing customized solutions and service to meet changing requirement of customers.

STRENGTH

- Stringent quality control with the latest testing equipments & instruments.
- Documentation support to all our customers.
- Strong focus on R & D
- Incessant troubleshooting
- Customer friendly work culture.



PRODUCT OVERVIEW

VITAMINS

- Niacinamide (Nicotinamide)
I.P. / B.P. / E.P. / U.S.P. / Cosmetic Grade / Technical Grade : Powder & Granules
- Niacin (Nicotinic Acid)
I.P. / B.P. / U.S.P. / Feed Grade / Technical Grade: Powder & Granules
- Benfotiamine IHS

CORTICOSTEROIDS (MICRONIZED)

- Clobetasol Propionate I.P. / B.P. / E.P. / U.S.P.
- Mometasone Furoate I.P. / B.P. / U.S.P. / E.P.
- Betamethasone Dipropionate I.P. / B.P. / E.P. / U.S.P.
- Beclomethasone Dipropionate I.P. / B.P. / E.P. / U.S.P.
- Betamethasone Valerate I.P. / B.P. / E.P. / U.S.P.
- Betametasone Sodium Phosphate I.P. / B.P. / E.P. / U.S.P.
- Dexamethasone Sodium Phosphate I.P. / B.P. / E.P. / U.S.P.
- Deflazacort IHS

TROPICAL ANTIBIOTIC

- Mupirocin I.P / B.P. / E.P. / U.S.P.

Note:
We offer all these
Products in Particle size
as per customer
requirement !!

**D.M.F. available for all
our Products !!**



PRODUCTION SITE OVERVIEW

THE FACILITY INCLUDE:

- Separate Dedicated G.M.P. Manufacturing facility for Vitamin B3 & Corticosteroids
- Proper division of Classified & non Classified area with positive pressure differentials.
- All critical operations have independent AHU'S with terminal HEPA filters.
- Epoxy flooring
- Control temperature NMT 25° C & Humidity 60%
- In House Digital Micronizer.
- 24-Hour 100 % Power Backup Generators.
- Chilling Plant
- Steam Boilers
- ETP Plant

Agro Cool India Ltd production site is situated in Northern Part of India at Charkhi Dadri in Haryana which is around 95km from New Delhi and is well connected by Road & Rail. The manufacturing site compasses area of 7526 sq meters, the cover area being 3650 sq meters.

WATER SYSTEM

Agro Cool India Ltd has complete SS Purified Water in-house Plant with SS pipelines which produces water as per I P / B P / U S P standard for our own production purpose. Purified water is collected in the DM water SS storage tank through SS pipeline. In the storage tank water is stored at 80°C temperature and distributed to users point passing through UV light. This water is continuously kept in circulation for the un-stangancy to avoid the microbial growth.





QUALITY

Quality is major priority at Agro Cool India Ltd. We are committed to total customer satisfaction by providing quality products under time abiding regulations. We strive to continuously improve our performance through effective process control and continuous review of the quality management system. Quality is built into everything we do. Quality at Agro Cool India is as a result of sincere effort, skillful execution, intelligent direction and high intention.

QUALITY CONTROL

Agro Cool India Ltd has an independent Quality Control Lab separate from the production area which is manned by qualified and experienced staff. Our QC lab is divided into three sections: **Chemical Lab, Instrumentation Lab, Microbiological Lab.**

Our Q.C instrumentation lab is equipped with all the latest sensitive and sophisticated instrument for analysis with GLP certification. We have in-house perfection testing with **HPLC's, GC-MS, UV, GC for Solvent testing, FTIR, Malvern Particle Size Analyser, Digital Automatic KF Moisture, Digital Automatic Melting Point & many more...**

MICROBIOLOGICAL LAB

Agro Cool India Ltd has a well equipped Microbiological lab for our Product Testing & Water Testing. Our microbiology lab uses good practices ensuring that all the tests performed by experienced certified microbiologist are in a very hygienic and disinfected Class A,B,D environment using excellent quality devices to get accurate results.

R&D LAB

Research and Development is a very crucial & essential part of our organization. Development of New Product Process to meet the ever-changing needs of the market has been the main focus of our R&D effort, apart from Quality Improvement and Increased Output of running products. A highly qualified team is constantly working on new processes, Improvement in present process and development of various bulk drugs, which are in pipeline.



QUALITY ASSURANCE

Our QA team ensures that the products we develop takes into account the requirements of Good Manufacturing Practices and Good Laboratory Practices. The Quality Assurance Department ensures that the manufacturing facilities and procedures are standardized to provide international quality attributes to the products consistently for each batch through a well-documented, validated and audited system. Our QA & Regulatory Affair Department have been trained to make high quality technical dossier's in CTD format to support smooth & fast registration of the product. Systems, well in place, to handle items such as:

- Documentation and Control
- Stability Studies
- Vendor approval system
- Training
- Qualification, Validation and Calibration.

PACKAGING

- HDPE Drums (Food Grade)
- Jumbo Bags
- Corrugated Box
- Fiber Drums
- Aluminum Jar Packing



CERTIFICATIONS

OFFICE OF THE STATE DRUGS CONTROLLER, HARYANA
FOOD AND DRUG ADMINISTRATION,
HARYANA, PANCHKULA

G.M.P. CERTIFICATE

This is to certify that M/s. Agro Cool India Ltd., Ghikara Road, Charkhi Dadr, Distt. Bhiwani, Haryana (India) is holding Drug Manufacturing Licenses on Form 28 & 28 bearing No. 991-05N(1) & 633-B(1) under the Drug and Cosmetics Act, 1940 and the Rules 1945 thereunder which are valid up to 31.07.2021 for manufacturing for sale of Bulk Drugs (APIs) categories of drugs formulations approved by this department. The firm is subject to periodical inspection by this department.

The firm, by and large, is following GOOD MANUFACTURING PRACTICES as stipulated under the provisions of Revised Schedule "M" of Drugs & Cosmetics Rules, 1945.

The firm should however carry out self-inspection from time to time to ensure that the requirements of Good Manufacturing Practices are complied with.

This certificate is valid for two years from the date of issue.

Dated: 25-11-2017
Place: Panchkula

LAL MOHAR GOEL
Assistant State Drugs Controller,
Food & Drug Administration,
PANCHKULA (Haryana)

GMP Certification

CERTIFICATE OF PHARMACEUTICAL PRODUCT
(This certificate is given to the manufacturer by the State Drugs Controller, Haryana, Panchkula)

1. Name of the product: **Nicotinamide BP**

2. Manufacturer's Name: **M/s. Agro Cool India Ltd., Ghikara Road, Charkhi Dadr, Distt. Bhiwani, Haryana, India**

3. Manufacturer's Address: **Ghikara Road, Charkhi Dadr, Distt. Bhiwani, Haryana, India**

4. Date of issue: **25-11-2017**

5. Validity: **31-07-2021**

6. Remarks: **Good Manufacturing Practices (GMP) are followed.**

7. Signature of the State Drugs Controller: **LAL MOHAR GOEL**

8. Place: **Panchkula**

COPP Certification

OFFICE OF THE STATE DRUGS CONTROLLER, HARYANA
LICENSING AUTHORITY FOOD AND DRUGS ADMINISTRATION,
HARYANA, PANCHKULA

SITE CERTIFICATE
(As per WHO-GMP Certification Scheme)

On the basis of the Joint inspection carried out on 18.11.2017 and 19.11.2017 and subsequent compliance verification on 31.03.2018 of M/s. Agro Cool India Ltd., Ghikara Road, Charkhi Dadr, Distt. Bhiwani (Haryana), it is certified that the site complies with the WHO-GMP certification scheme for categories and activities listed in Table 1.

Name and Address of Site:
M/s. Agro Cool India Ltd., Ghikara Road, Charkhi Dadr, Distt. Bhiwani, Haryana, India

Manufacturer's License No.: **633-B(1) & 991-05N(1)**

S. No.	Pharmaceutical Product (a) Starting Material (b)	Activities
1.	Nicotinamide BP	Production, Packing & Quality Control

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

The Certificate is valid from 15.01.2017 to 14.01.2020 subject to the verification of license & firm will apply for renewal within prescribed time limit and 1 license renewal if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP as specified under WHO-GMP Certification Scheme.

Address of the Certifying Authority:
STATE DRUGS CONTROLLER, LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION,
HARYANA, PANCHKULA.

LAL MOHAR GOEL
Assistant State Drugs Controller,
Food & Drug Administration,
PANCHKULA (Haryana)

To: **M/s. Agro Cool India Ltd., Ghikara Road, Charkhi Dadr, Distt. Bhiwani, Haryana, India**

No. 211-10mg-2018/17-18 Date: 25/11/17

WHO GMP Certification

intertek
Test. Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Agro Cool India Limited

Manufacturer's License No.: **633-B(1) & 991-05N(1)**

ISO 9001:2015

The management system is applicable to:

Manufacturing and Marketing of Nicotinamide BP (GMP) under 991-05N(1) and 633-B(1) in the form of Tablets, Capsules, Syringes, etc.

Certificate Number: **058001**
Initial Certification Date: **05 September 2018**
Date of Certification Review: **05 September 2020**
Expiry Date: **05 September 2022**
Valid Until: **05 September 2022**

Celestine
Principal, Business Assurance
Intertek Certification Limited, 200 Victoria Park, Silver Road, Derby DE1 1JL, United Kingdom

STATE DRUGS CONTROLLER, LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION,
HARYANA, PANCHKULA

ISO 9001:2015

intertek
Test. Quality. Assured.

CERTIFICATE OF CONFORMANCE

This is to certify that the management system of:

AGRO COOL INDIA LIMITED

Manufacturer's License No.: **633-B(1) & 991-05N(1)**

HACCP

International Code of Practice General
CAC/RCP 1-1969, Rev. 4-2003

The management system is applicable to:

Scope: Manufacturing (Production, Distribution, Control, Storage, Shipping, Storage & Packing) of Nicotinamide BP (GMP) under 991-05N(1) and 633-B(1) in the form of Tablets, Capsules, Syringes, etc.

Certificate Number: **058001**
Initial Certification Date: **05 September 2018**
Date of Certification Review: **05 September 2020**
Expiry Date: **05 September 2022**
Valid Until: **05 September 2022**

LAL MOHAR GOEL
Principal, Business Assurance
Intertek Certification Limited, 200 Victoria Park, Silver Road, Derby DE1 1JL, United Kingdom

STATE DRUGS CONTROLLER, LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION,
HARYANA, PANCHKULA

HACCP

STAR-K KOSHER CERTIFICATION

September 20, 2018
11 Tishrei 5779

Agro Cool India Ltd.
Ghikara Road, Charkhi Dadr
Distt. Bhiwani, Haryana 127 306
India

PLEASE NOTE THE FOLLOWING CONDITIONS OF CERTIFICATION:
All products listed below are Pareve.
All products listed below are Kosher for year-round use, excluding Passover.
All products listed below are certified Kosher when manufactured by Agro Cool India Ltd., Distt. Bhiwani, Haryana, India, as stated on original manufacturer's label.
This letter of certification is valid through August 31, 2019 and is subject to renewal at that time.

BRAND: **Agro Cool India Ltd.**

PRODUCT LISTING:
Nicotinamide BP (GMP)
Nicotinamide BP (GMP)

Eliyahu Shuman
Rabbi Eliezer Shuman
Director of Supervision

Effective Through 08/31/2019

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A NON-PROFIT AGENCY REPRESENTING THE KOSHER CONSUMER IN PROMOTING KASHRUS THROUGH EDUCATION, RESEARCH AND SUPERVISION

KOSHER (Star-K-Kosher)

Jamiat Ulama-Hind Halal Trust
Registration No. 2276

HALAL REGISTRATION CERTIFICATE

This is to certify that the establishment described below has been inspected and assessed by Jamiat Ulama-Hind Halal Trust and found to comply with Halal requirement.

Name of Company: **M/s. Agro Cool India Limited,**

Address: **GID-25, Pitampura (Near Madhuban Chowk), Delhi-110034, India**

Plant Address: **Ghikara Road, Charkhi Dadr (Haryana)-127306, India.**

Scope: **1. Nicotinamide & 2. Nicotin.**

Registration No.: **JUH/HRC/1423/2018.**

Issued on: **29-09-2018**

Validity: **29-09-2018 to 28-09-2019.**

Authorized Signatory:
Niaz Ahmed Farooqui
Secretary

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HALAL

OFFICE OF THE STATE DRUGS CONTROLLER, HARYANA
FOOD AND DRUG ADMINISTRATION,
HARYANA, PANCHKULA

G.L.P. CERTIFICATE

This is to certify that M/s. Agro Cool India Ltd., Ghikara Road, Charkhi Dadr, Distt. Bhiwani, Haryana (India), is holding Drugs Manufacturing Licenses No. 991-05N(1) & 633-B(1) on Form 28 & 25 respectively for carrying out manufacturing of drugs which is valid up to 31.07.2021.

The firm is having its own testing laboratory for testing and quality control requirements by and large in pursuance to the provision of Schedule L-1 of the Drugs and Cosmetics Act, 1940 and Rules 1945.

This certificate is valid up to 31.07.2021

LAL MOHAR GOEL
Assistant State Drugs Controller,
Food & Drug Administration,
PANCHKULA (Haryana)

GLP Certification (For Lab)

FAMI-QS
FEED SAFETY MANAGEMENT SYSTEM
SWISSCERT

FAMI-QS (For Feed Industry)

fssai
Food Safety and Standards Authority of India

FSSAI (For Food Industry)

EUROPEAN UNION GMP

EUGMP (Under Process)

STAR EXPORT HOUSE
RECOGNISED BY GOVT. OF INDIA
GOVT. RECOGNIZED STAR EXPORT HOUSE

Star Export House (Under Process)



Contact Us

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