



About Amishi Drugs & Chemicals Pvt. Ltd

Amishi Drugs & Chemicals Pvt. Ltd having professional promoter background with, Ultramodern Plant Situated in pollution free Industrial estate at Naroda, Ahmedabad, Gujarat, India. Established in 1983, AD&C has been working towards strengthening our manufacturing base and product portfolio. The company focuses on continuously reviewing opportunities in the pharmaceutical industry as well as other growing segments to offer new and innovative products. AD&C is a Technology driven company setting up high benchmarks for excellence in Product Quality and adherence to stringent delivery Schedule.

With the stricter regulatory compliances being implied in the Pharmaceutical, Cosmetic, Food industries the product requires more than just specifications. AD&C understands the challenges and is ready to excel to manufacture, analyze and certify the products. AD&C has successfully met this stupendous challenge of delivering range of products due to high quality manpower with proven skill sets and enviable processes with commitment to safety, health and environment. We are an FDA GMP halal Kosher certified company ISO 9001 - 2008.

Sodium Carboxymethyl Cellulose

Calcium carboxymethyl cellulose is a calcium salt of carboxymethyl cellulose. It is derived from purified cellulose or Alpha-cellulose.

Calcium is a divalent ion and which renders the end product insoluble in water but having high swelling property in water. Due to these properties the product is used as super disintegrate.



In certain type of tablet formulations in which normal disintegrates are not providing required disintegration time, the calcium CMC is successful disintegrate.

Application

- In Tablets
- As Disintegrating agent

Microcrystalline Cellulose

Micro Crystalline Cellulose is a purified and partially depolymerized crystalline powder, which is composed of porous particles. It is tasteless, odorless and white in color. We offer this powder in two grades - M CCP-101 and M CCP-102, according to I.P./USP/BP specifications. For its manufacturing, cellulose, collected from fibrous material, undergoes controlled hydrolysis with dilute mineral acid. The resulting product is this powder.



Application

It has high absorbent powers, and can be used as a suspending agent, tablet & capsule diluent.

Capstone

ADCL's M CCP are available in 2 grades M CCP 101(binder) and M CCP 102(disintegrator) acc. to IB/BP/USP based on their different sieving methods and moisture content.

Sodium Starch Glycolate

Sodium Starch Glycolate is a very fine free flowing powder that is white or off white in color and has almost no odor. Its property of insolubility is remarkable, with complete insolubility in most organic solvents, and even in water. It is a sodium salt of carboxyl ether of starch, and is appreciated for its stability and binding properties. It finds much usage in pharmaceutical industry, to disintegrate tablet formulations & capsules and in tablets that employ wet-granulation or direct compression processes.



Application

To disintegrate tablet formulations & capsules and in tablets that employ wet-granulation or direct compression processes. This powder is able to retain its disintegrating efficiency even if it is in close proximity of hydrophobic excipients.

Capstone

ADCL SSG is available with corn starch or potato starch derivative. Available in IP/BP/USP.

Die Press Starch (Pregelatinized Starch)

Starch is a naturally occurring most frequently used excipient in solid dosage forms. It is a multipurpose product in that it can also be used as a disintegrating agent and as a binder in the form of starch paste.

Die - press starch is a Starch which has been physically modified to be free flowing and directly compressible. Consequently it is exceptionally adaptable in tablet and capsule formulations and widely accepted as a multipurpose excipient in all solid dosage forms.



Application

- In Direct Compression of tablets, when drug to excipient ratio is low.
- In Capsule filling operation on high speed capsule filling machine to reduce rejection level.
- In Wet granulation process, when drug to excipient ratio is high.

Capstone

ADCL is one of the very few company's to manufacture Die-Press Starch.

Silver Sulfadiazine

- Silver Sulfadiazine has broad antimicrobial activity against Gram positive and Gram negative bacteria, yeasts and fungi.
- It has also been reported to be active in vitro against herpes virus and Treponema pallidum.
- This antimicrobial action is attributable to both Silver and Sulfadiazine and antagonized by P-aminobenzoic acid.



- It is a sulphonamide which is not inactivated by pus and serum
- It is used as a 1% cream in 3 to 5 mm thickness, for the prevention and treatment of infection particularly by Pseudomonas aeruginosa, in second & third degree burns.

Application

- In topical formulation like creams, for treatment of severe burns.

Croscarmellose Sodium

Croscarmellose Sodium is cross-linked sodium carboxymethyl methyl cellulose without use of any cross-linking agent. It is insoluble, white to greyish white free flowing powder.

In compressed tablets croscarmellose sodium will prove to be an excellent disintegrant Inclusion of 1 - 3 % concentration of tablet weight is the typical range is mostly sufficient.



Good water uptake, Rapid swelling, Relatively long fiber length for effective fluid channeling excellent long term dissolution stability, Dissolution / disintegration independent to tablet hardness are the feature and benefits of croscarmellose sodium.

Application

- Superior dissolution and disintegrant for pharmaceutical formulations like tablets Capsule and Caplet.

Certificates:



Certificate of Registration

This is to certify that the Management System of:
Amishi Drugs and Chemicals Pvt. Ltd.
Plot No. 621 & 622, Phase IV, GIDC Naroda, Ahmedabad-382 330, Gujarat, India
has been approved by Alcumus ISOQR and is compliant with the requirements of:
ISO 9001: 2015

Certificate Number: 6843-QMS
Initial Registration Date: 22 April 2008
Re-issue Date: 06 April 2017
Expiry Date: 22 April 2020

Scope of Registration:
Manufacture and supply of Bulk Drug such as magnesium stearate, Sodium Starch glycolate, Pregelatinized starch, Starch (IP/BP/USP Grade), Croscarmellose Sodium, Calcium Carboxymethyl Cellulose, Sodium Carboxymethyl cellulose, Microcrystalline cellulose and silver sulfadiazine

Signed:
Steve Stubble, Technical Director
(on behalf of Alcumus ISOQR)

[Signature]

This certificate will remain current subject to the company maintaining its system to the required standard. This will be monitored regularly by Alcumus ISOQR. Further clarification regarding the scope of this certificate and the applicability of the relevant standards' requirements may be obtained by consulting Alcumus ISOQR.

Alcumus ISOQR Limited Coburn Court, 1 Blackmore Road, Strefford, Manchester M32 0QY | +44 (0)161 865 3699 | +44 (0)161 865 3685
This certificate is the property of Alcumus ISOQR and must be returned on request.





Food & Drugs Control Administration
BLOCK NO. 1, 1ST FLOOR, D. JIVRAJI MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010

Certificate No. : **S-GMP/1806895**

G.M.P. CERTIFICATE

This is to certify that **M/s. AMISHI DRUGS & CHEMICALS PVT. LTD., PLOT NO. 621, 622, PHASE - IV G.I.D.C., NARODA, AHMEDABAD - 382 330**, is holding valid drug manufacturing license in Form No. 25 bearing No. 6/25/636 issued by this administration under the provisions of Drugs & Cosmetics Act 1940 & Rules there under. Under the said license the firm is permitted to manufacture & sell drugs covered under the following categories.

dosage Form (s)	Category (ies)
Bulk Drugs (APIs & Excipients)	General

The firm has employed competent technical staff to undertake manufacturing & testing of the permitted drugs. They are following **GOOD MANUFACTURING PRACTICES** in manufacturing and testing as laid down under the **REVISED SCHEDULE-M** of Drugs & Cosmetics Act 1940 & Rules There under.
The manufacturing plant is subjected to inspection at suitable intervals by competent authority.
This certificate is valid from **DT : 25/06/2018 to 24/06/2020**.

[Signature]
Dr. S. S. KOSHIDA
Commissioner
Food & Drugs Control Administration
Gandhinagar, Gujarat State

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KOSHER INSPECTION SERVICE - INDIA

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KOSHER CERTIFICATE


15th February, 2019

I hereby confirm that I have visited the factory of **M/s. AMISHI DRUGS & CHEMICALS PVT. LTD., NARODA, AHMEDABAD, INDIA** and have conducted the necessary KASHRUT inspection into their production / processing / ingredients / raw materials / CHAMETZ (LEAVEN) of their products of:

- 1) SODIUM STARCH GLYCOLATE
- 2) CROSCARMELOSE SODIUM
- 3) MAGNESIUM STEARATE
- 4) SODIUM CARBOXY METHYL CELLULOSE
- 5) MICROCRYSTALLINE CELLULOSE
- 6) CALCIUM CARBOXY METHYL CELLULOSE
- 7) DIE PRESS STARCH (PREGELATINISED STARCH)
- 8) SILVER SULFADIAZINE

I hereby certify that the above products do not contain any prohibitory or Non-Kosher ingredients / chemicals / raw materials and are manufactured / processed only from: 1) STARCH POTATO / CORN, ACID & CHEMICALS. 2) CELLULOSE, ACID & CHEMICALS 3) STEARIC ACID, MAGNESIUM SULPHATE & SODIUM HYDROXIDE 4) PULP, CAUSTIC SODA, MONO CHLORO ACETIC ACID & METHANOL / ETHANOL 5) SILVER NITRATE 6) SULFADIAZINE. These products comply with the LAWS OF KASHRUTH and are processed/manufactured under HALACHA REGULATIONS. No animal fats or meat bones are used in the processing / manufacturing of the above products. Therefore, the above mentioned products are strictly KOSHER & PAREVE and can be consumed by Observant Jews without concern or can be used in KOSHER FOOD INDUSTRIES and in KOSHER PRODUCTS for the whole year round.

This certificate is NOT VALID FOR PASSOVER.
No products other than the above mentioned products are manufactured / processed in their Plant / Unit.
This company is under my regular supervision.

These products must carry the  Seal of KASHRUT on the label.

This certificate is valid upto 14th February, 2020 and is subject to RENEWAL at that time.

[Signature]
RABBI / MASHGIYAH AVRAHAM BINYAMIN

[Handwritten notes and stamps]