

2011



PRODUCTS FOR PHARMACEUTICAL INDUSTRY



NATURE BIOCHEM

304/2/I, Seetharam Industrial Estate, MES Road,
Jalahalli Village, Bangalore 5600013, Karnataka, India

Telefax: +91-80-23451779, Mobile: +91 9845211481

E-mail: info@naturebiochem.com

Our Services to Buyers

NATURE BIOCHEM can source products for you from our suppliers in the China, Europe, North America and the Far East . We welcome your enquiries, regardless of volume, for any of our product range consisting of :

- **Active Pharmaceutical Ingredients.**
- **Natural Products and Supplements**
- **Excepients**



If you are interested in exploring the possibilities in more depth, please **contact us** with your details and the nature of your enquiry.

BP - British Pharmacopoeia

CP - Chinese Pharmacopoeia

EP - European Pharmacopoeia

JP - Japanese Pharmacopoeia

USP – United States Pharmacopoeia



*** Product exploration, including development, sales and offer for sale are performed where permissible by patent law. This presentation is not and should not constitute as an offer for sale in territories where it is not permitted by law.

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Pharmaceutical Products

Among other drugs, we source and supply (APIs) Active Pharmaceutical Ingredients, from a range of international sources. We do not stock them.



Natural Products and Supplements

- Herbals
- Supplements
 - Dietary
 - Non-dietary
 - Sport
 - Food
- Extracts
- Essential oils



Excipients

- [Antiadherents](#)
- [Binders](#)
- [Coatings](#)
 - [Changing the dissolution rates of active species](#)
- [Disintegrants](#)
- [Fillers and diluents](#)
- [Flavours](#)
- [Colours](#)
- [Lubricants](#)
- [Glidants](#)
- [Preservatives](#)
- [Sorbents](#)
- [Sweeteners](#)

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PRODUCT SPOTLIGHT:

1) Enzymatic Synthesized L-ascorbyl Palmitate (L-AP)

L-AP, which is ascorbyl palmitate, is manufactured using the enzymic technology instead of the traditional chemosynthesis, so has much more purity. L-Ascorbyl palmitate is also marketed as "vitamin C ester", is an ester formed from ascorbic acid and palmitic acid creating a fat-soluble form of vitamin C via the enzymic synthesized technology. In addition to its use as a source of vitamin C, it is also used as an antioxidant food additive (E number E304). It is available in USP and BP as pharmaceutical aid. It is the only antioxidant allowed to be added in the formulas for infant and growing up children. As an antioxidant, it is far safer than any other commercially used synthesized antioxidants, such as BHA, BHT, as well as TBHQ

Unique Characteristics:

- Fully Natural: pure natural raw material, plus bio-catalyzed processes: Nothing but lipase and necessary organic solvents allowed to be used for the manufacturing of food, such as acetone and hexane, have been used during whole the process, so the product can be regarded as Equivalent of Natural Product;
- Absolutely No Residues: Neither Thionyl Chloride, no Methylene Dichloride, no N-dimethyl formamide have been used. And the processes such as distillation, neutralization, and rinsing have all been avoided. So there is no potential residue of chemical hazards, and heavy metals.
- Guaranteed Safety: Very good color, excellent purity, and extremely prolonged shelf life. Particularly suitable to be used as pharmaceutical aid, antioxidant of formula for infant and growing-up children, can be directly administered as nutraceuticals, as well can be used as an active ingredients of cosmetics.
- Strengthened Anti-oxidation function: It is the highly region-selective specificity of lipase which makes sure that the 2- and 3- hydroxyl group, the functional group of L-AP as antioxidant, of our product is fully available. It is responsible for the fact that the antioxidant activity of enzymatic synthesized L-AP is 50% higher than chemical synthesized L-AP.

2. **GABA and L-theanine** are kinds of natural amino acid, which is composition of non-protein. We can provide the natural base and chemosynthesis.

3. **Nisin** is the natural preservative can have the wide application.

4. **FOS (Fructo oligosaccharide) and GOS(Galacto oligosaccharide)** are the functional sweetener

5. **Polylysine** (natural preservative), better than Nisin.

6. **Ornithine and citrulline** are also made using the fermentation technology.

7. **Tween and Span** (Pharmaceutical intermediates), made by the fermentation technology.

8. **Tagatose** is the functional sweetener, and diabetics can eat without effect on blood sugar.

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SPECIAL FEATURE ON “EXCIPIENTS”: “WE CAN PROVIDE ALL EXCIPIENTS”:

An excipient is generally a pharmacologically inactive substance used as a carrier for the active ingredients of a medication. In many cases, an "active" substance (such as acetylsalicylic acid) may not be easily administered and absorbed by the human body; in such cases the substance in question may be dissolved into or mixed with an excipient. Excipients are also sometimes used to bulk up formulations that contain very potent active ingredients, to allow for convenient and accurate dosage. In addition to their use in the single-dosage quantity, excipients can be used in the manufacturing process to aid in the handling of the active substance concerned. Depending on the route of administration, and form of medication, different excipients may be used. For oral administration tablets and capsules are used. Suppositories are used for rectal administration.

Often, once an active ingredient has been purified, it cannot stay in purified form for long. In many cases it will denature, fall out of solution, or stick to the sides of the container. To stabilize the active ingredient, excipients are added, ensuring that the active ingredient stays "active", and, just as importantly, stable for a sufficiently long period of time that the shelf-life of the product makes it competitive with other products. Thus, the formulation of excipients in many cases is considered a trade secret.

Pharmaceutical codes require that all ingredients in drugs, as well as their chemical decomposition products, be identified and guaranteed to be safe. For this reason, excipients are only used when absolutely necessary and in the smallest amounts possible.

Antiadherents

Antiadherents are used to reduce the adhesion between the powder (granules) and the punch faces and thus prevent sticking to tablet punches. They are also used to help protect tablets from sticking. Most commonly used is magnesium stearate.

Binders

Binders hold the ingredients in a tablet together. Binders ensure that tablets and granules can be formed with required mechanical strength, and give volume to low active dose tablets. Binders are usually:

- Saccharides and their derivatives:
 - Disaccharides: sucrose, lactose;
 - Polysaccharides and their derivatives: starches, cellulose or modified cellulose such as microcrystalline cellulose and cellulose ethers such as hydroxypropyl cellulose (HPC);
 - Sugar alcohols such as xylitol, sorbitol or maltitol;
- Protein: gelatin;
- Synthetic polymers: polyvinylpyrrolidone (PVP), polyethylene glycol (PEG)...

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Binders are classified according to their application:

- Solution binders are dissolved in a solvent (for example water or alcohol can be used in wet granulation processes). Examples include gelatin, cellulose, cellulose derivatives, polyvinylpyrrolidone, starch, sucrose and polyethylene glycol.
- Dry binders are added to the powder blend, either after a wet granulation step, or as part of a direct powder compression (DC) formula. Examples include cellulose, methyl cellulose, polyvinylpyrrolidone and polyethylene glycol.

Coatings

Tablet coatings protect tablet ingredients from deterioration by moisture in the air and make large or unpleasant-tasting tablets easier to swallow. For most coated tablets, a cellulose ether hydroxypropyl methylcellulose (HPMC) film coating is used which is free of sugar and potential allergens. Occasionally, other coating materials are used, for example synthetic polymers, shellac, corn protein zein or other polysaccharides. Capsules are coated with gelatin.

Changing the dissolution rates of active species

Enterics control the rate of drug release and determine where the drug will be released in the digestive tract

An enteric coating is a barrier applied to oral medication that controls the location in the digestive system, where it is absorbed. *Enteric* refers to the small intestine, therefore enteric coatings prevent release of medication before it reaches the small intestine.

Most enteric coatings work by presenting a surface that is stable at the highly acidic pH found in the stomach, but breaks down rapidly at a less acidic (relatively more basic) pH. For example, they will not dissolve in the acidic juices of the stomach (pH ~3), but they will in the alkaline (pH 7-9) environment present in the small intestine. Materials used for enteric coatings include fatty acids, waxes, shellac, plastics, and plant fibers.

Drugs that have an irritant effect on the stomach, such as aspirin, can be coated with a substance that will dissolve only in the small intestine. Likewise, certain groups of azoles (esomeprazole, omeprazole, pan and all grouped azoles) are acid-unstable. For such types of drugs, enteric coating added to the formulation tends to avoid the stomach's acidic exposure, delivering them instead to a basic pH environment (intestine's pH 5.5 and above) where they do not degrade, and give their desired action.

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Recently, some companies have begun to utilize enteric coatings on fish oil (omega-3 fatty acids) supplements. The coating prevents the fish oil capsules from being digested in the stomach, which has been known to cause a fishy reflux (fish burps).

Sometimes the abbreviation "EC" is added beside the name of the drug to indicate that it has an enteric coating.

Composition of coatings

- methyl acrylate-methacrylic acid copolymers
- cellulose acetate succinate
- hydroxy propyl methyl cellulose phthalate
- hydroxy propyl methyl cellulose acetate succinate (hypromellose acetate succinate)
- polyvinyl acetate phthalate (PVAP)
- methyl methacrylate-methacrylic acid copolymers
- Sodium alginate and stearic acid

Disintegrants

Disintegrants expand and dissolve when wet causing the tablet to break apart in the digestive tract, releasing the active ingredients for absorption.

They ensure that when the tablet is in contact with water, it rapidly breaks down into smaller fragments, facilitating dissolution.

Examples of disintegrants include:

- Crosslinked polymers: crosslinked polyvinylpyrrolidone (crospovidone), crosslinked sodium carboxymethyl cellulose (croscarmellose sodium).
- The modified starch sodium starch glycolate...

Fillers and diluents

Fillers fill out the size of a tablet or capsule, making it practical to produce and convenient for the consumer to use. By increasing the bulk volume, the fillers make it possible for the final product to have the proper volume for patient handling.

A good filler must be inert, compatible with the other components of the formulation, non-hygroscopic, relatively cheap, compactible, and preferably tasteless or pleasant tasting.

Plant cellulose (pure plant filler) is popular filler in tablets or hard gelatin capsules. Dibasic calcium phosphate is popular tablet filler. A range of vegetable fats and oils can be used in soft gelatin capsules.

Other examples of fillers include: lactose, sucrose, glucose, mannitol, sorbitol, calcium carbonate, and magnesium stearate.

Flavours

Flavours can be used to mask unpleasant tasting active ingredients and improve the acceptance that the patient will complete a course of medication. Flavourings may be natural (e.g. fruit extract) or artificial.

For example, to improve

- a bitter product - mint, cherry or anise may be used
- a salty product - peach, apricot or liquorice may be used
- a sour product - raspberry or liquorice may be used
- an excessively sweet product - vanilla may be used

Colours

Colours are added to improve the appearance of a formulation. Colour consistency is important as it allows easy identification of a medication.

Lubricants

Lubricants prevent ingredients from clumping together and from sticking to the tablet punches or capsule filling machine. Lubricants also ensure that tablet formation and ejection can occur with low friction between the solid and die wall.

Common minerals like talc or silica, and fats, e.g. vegetable stearin, magnesium stearate or stearic acid are the most frequently used lubricants in tablets or hard gelatin capsules. Lubricants are agents added in small quantities to tablet and capsule formulations to improve certain processing characteristics.

There are three roles identified with lubricants as follows:

1. True Lubricant Role:

- To decrease friction at the interface between a tablet's surface and the die wall during ejection and reduce wear on punches & dies.

2. Anti-adherent Role:

- Prevent sticking to punch faces or in the case of encapsulation, lubricants
- Prevent sticking to machine dosators, tamping pins, etc

3. Glidant Role:

- Enhance product flow by reducing interparticulate friction.

There are two major types of lubricants:

1. Hydrophilic - Generally poor lubricants, no glidant or anti-adherent properties.
2. Hydrophobic - Most widely used lubricants in use today are of the hydrophobic category. Hydrophobic lubricants are generally good lubricants and are usually effective at relatively low concentrations. Many also have both anti- adherent and glidant properties. For these reasons, hydrophobic lubricants are used much more frequently than hydrophilic compounds. Examples include magnesium stearate.

Glidants

Glidants are used to promote powder flow by reducing interparticle friction and cohesion. These are used in combination with lubricants as they have no ability to reduce die wall friction. Examples include fumed silica, talc, and magnesium carbonate.

Preservatives

Some typical preservatives used in pharmaceutical formulations are

- Antioxidants like vitamin A, vitamin E, vitamin C, retinyl palmitate, and selenium
- The amino acids cysteine and methionine
- Citric acid and sodium citrate
- Synthetic preservatives like the parabens: methyl paraben and propyl paraben.

Sorbents

Sorbents are used for tablet/capsule moisture-proofing by limited fluid sorbing (taking up of a liquid or a gas either by adsorption or by absorption) in a dry state.

Sweeteners

Sweeteners are added to make the ingredients more palatable, especially in chewable tablets such as antacid or liquids like cough syrup. Sugar can be used to mask unpleasant tastes or smells.

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LATEST NME'S APPROVED BY CDER IN CALANDER YEAR 2011:
FDA report on New Molecular Entities / Significant Biologicals

Brand	Generic	Company	Description
Adcetris	brentuximab vedotin	Seattle Genetics	A CD30-directed antibody-drug conjugate for certain types of advanced lymphomas.
Anascorp	Centruroides immune F(ab)2	Rare Disease Therapeutics	An antivenom for scorpion stings.
Arcapta Neohaler	indacaterol	Novartis	A long-acting beta-agonist inhaler for COPD.
Benlysta	belimumab	Human Genome Sciences/GSK	A B-lymphocyte stimulator-specific inhibitor for systemic lupus erythematosus.
Brilinta	ticagrelor	AstraZeneca	An antiplatelet for patients with acute coronary syndrome (ACS).
Caprelsa	vandetanib	AstraZeneca	An oral kinase inhibitor for advanced medullary thyroid cancer.
Corifact	factor XIII	CSL Behring	Factor XIII concentrate (Human) to prevent bleeding in patients with congenital factor XIII deficiency.
Daliresp	roflumilast	Forest	An oral phosphodiesterase type 4 inhibitor to reduce the risk of COPD exacerbations.
DaTscan	ioflupane I 123	GE Healthcare	Diagnostic imaging agent to evaluate patients with suspected Parkinsonian syndromes.
Dificid	fidaxomicin	Optimer Pharm.	A macrolide antibiotic for treatment of <i>Clostridium difficile</i> -associated diarrhea.
Edarbi	azilsartan	Takeda	An angiotensin II receptor blocker (ARB) for hypertension.
Edurant	rilpivirine	Tibotec	A non-nucleoside reverse transcriptase inhibitor (NNRTI) for HIV-1 infection.
Erwinaze	asparaginase <i>Erwinia chrysanthemi</i>	EUSA Pharma	An <i>E. chrysanthemi</i> -derived asparaginase for acute lymphoblastic leukemia in patients who are allergic to <i>E. coli</i> -derived asparaginase.
Eylea	aflibercept	Regeneron Pharm.	An intravitreal injection for wet age-related macular degeneration (AMD).
Ferriprox	deferiprone	ApoPharma	An oral iron chelator for iron overload due to

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			blood transfusions in patients with thalassemia.
Firazyr	icatibant	Shire Human Genetic Therapies	A bradykinin B2 receptor antagonist for acute attacks of hereditary angioedema (HAE).
Fluzone Intradermal	influenza vaccine	Sanofi Pasteur	An intradermal seasonal influenza vaccine for patients ages 18 through 64 years.
Gadavist	gadobutrol	Bayer	A gadolinium-based contrast agent for CNS scans.
Horizant	gabapentin enacarbil	GSK	A gabapentin prodrug for restless legs syndrome.
Incivek	telaprevir	Vertex Pharm.	An oral protease inhibitor for chronic hepatitis C.
Jakafi	ruxolitinib	Incyte Corp.	A kinase inhibitor for the bone marrow disease myelofibrosis.
Natroba	spinosad	ParaPRO/Pernix	Topical pediculicide for treatment of head lice.
Nulojix	belatacept	BMS	An immunosuppressant to prevent organ rejection after a kidney transplant.
Onfi	clobazam	Lundbeck	An oral benzodiazepine for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome.
Potiga	ezogabine	GSK	An anticonvulsant for treatment of partial-onset seizures.
Tradjenta	linagliptin	Boehringer Ingelheim	A DPP-4 inhibitor for type 2 diabetes.
Victrelis	boceprevir	Merck	An oral protease inhibitor for chronic hepatitis C.
Viibryd	vilazodone	Trovis Pharm.	An SSRI/serotonin receptor partial agonist for depression.
Xalkori	crizotinib	Pfizer	A kinase inhibitor for advanced non-small cell lung cancer.
Xarelto	rivaroxaban	Janssen	An oral factor Xa inhibitor for prevention of DVT post knee or hip replacement surgery.

Yervoy	ipilimumab	BMS	A cytotoxic T-lymphocyte antigen 4-blocking antibody for late stage melanoma.
Zelboraf	vemurafenib	Genentech	A kinase inhibitor for advanced melanoma.
Zytiga	abiraterone	Centocor Ortho Biotech	A CYP17 inhibitor for advanced prostate cancer.

Significant New Dosage Forms

Brand	Generic	Company	Description
Abstral	fentanyl	ProStrakan	Sublingual tablets for management of breakthrough pain in cancer patients tolerant to opioid therapy.
AndroGel	testosterone	Abbott	New concentrated formulation (1.62%) topical gel for hypogonadism.
Banzel	rufinamide	Eisai	New oral suspension formulation for seizures.
Combivent Respimat	ipratropium/albuterol	Boehringer Ingelheim	An inhalation spray for COPD that does not contain chlorofluorocarbons (CFCs).
Complera	emtricitabine/ rilpivirine/ tenofovir	Gilead Sciences	New combination formulation for HIV-1 infection in treatment-naïve adults.

Drug Withdrawals

Brand	Generic	Company	Description
Xigris	drotrecogin alfa	Lilly	Withdrawn from the market due to failure to show survival benefit.

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