DHA (Docosahexaenoic acid)

EPA (Eicosapentaenoic acid)

-FREE FATTY ACID POWDER FORMS

International Patent Application
PCT/IN2012/000309
PCT/IN2012/000310

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About Company

NVAS Biochem Pvt. Ltd and Central India Pharmaceuticals

• Dynamic, research based, global company in India, known for its innovative quality products and services in human health care and having Industrial Experience over 17 years for manufacturing Herbal Formulation and Fine Chemicals .

• DHA and EPA powders produced by the company, using a Innovative and Patented technology offers several advantages over the conventionally available forms and are also cost competitive.

• Company has already setup a manufacturing facility with a capacity to produce max. 400 kgs of DHA and 100 kgs of EPA per month.

Few more products are in Pipeline, for more details follow the link www.nvasbiochem.com

Patent Portfolio of the Company:

- PCT/IN2012/000309 : Isolation of DHA in its directly compressible powder form
- PCT/IN2012/000310 : Isolation of EPA in its directly compressible powder form
- Isolation of indole alkaloids from Moringa oleifera as anticancer agent. Filed application No. 2331/MUM/2010
- Process for isolation of anticancer agent a new alkaloids from Moringa oleifera. Filed application No. 2332/MUM/2010
- Process for isolation of anticancer agent from Salaria reticulata Filed application No. 2333/MUM/2010
- Composition of Shorea robusta and Azadirachata indica as antifungal. Filed application No. 2328/MUM/2010
- Herbal composition for the treatment of oligospermia and to increase the sperm motility. Patent No. 227492.
- Contraceptive effects of saponins from Acacia concinna DC Patent No.225314.

Background :

• Docosahexaenoic acid (DHA) and Eicosapentaenoic acid (EPA) are omega-3 fatty acid that are obtained in the human diet by eating oily fish or fish oil e.g., cod liver, herring, mackerel, salmon, menhaden and sardine.

• The human body converts alpha-linolenic acid (ALA) to EPA, but this is much less efficient than the absorption of EPA from food containing it. Therefore an appropriate supply of which must be ensured.

• Attempts were made to isolate EPA from various sources. Previously attempted research resulted into the free fatty acids, which are in the liquid form.

• Looking at the immense potential of this product in the commercial market, several attempts were made to incorporate these fatty acids in powder form by means of adsorption, encapsulation, spray drying the emulsion and direct drying of algae source of these fatty acids to get powder.

Disadvantages of Existing Technologies/Products:

• The main concern with existing technologies/products isolated using these earlier existing technologies are difficulty in achieving desired **purity, desired levels of separation of fatty acids, stability of product and incorporation in the dry dosage forms and nutrition products along with limitations of compressibility**.

• The products in the market are **either soft gel capsules having DHA and/or EPA as esters in oil form (mostly mixtures) or the spray dried microencapsulated powder having bioavailability of not more than 22%.**

It is scientific to say that "the DHA and EPA in its free fatty acid form will offer excellent bioavailability , that could lead to better incorporation in the target organs.

The proposed isolation method yields DHA and EPA in its free fatty acid powder form and offers excellent bioavailability of above 90 %.

ISOLATION OF DHA & EPA: PROPOSED METHOD

• Docosahexaenoic acid (DHA) and Eicosapentaenoic acid (EPA) are available in its free fatty acid form, isolated using a unique process of isolation thereof from oils and fats of natural origin having Docosahexaenoic acid (DHA) or Eicosapentaenoic acid (EPA) attached to triglycerides.

• The isolation process comprises

(i) selecting any one of oils and fats from natural sources having EPA/DHA attached to triglycerides,

(ii) adding equal quantity of any one or mixture of alcoholic sodium hydroxide and potassium hydroxide to form a reaction mixture,

(iii) stirring the mixture for separating in to two layers

(iv) discarding an upper layer containing lower fatty acids, the triglycerides and other impurities,

(v) adding a ketone to a lower layer of the two layer to form a second mixture,

(vi) keeping aside the second mixture to precipitate higher free fatty acids,

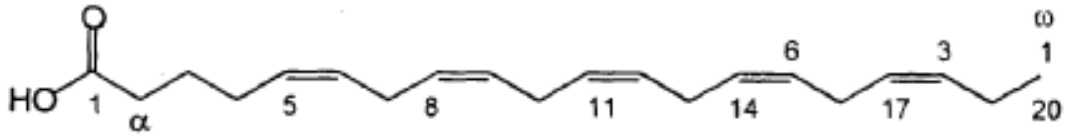
(vii) filtering the second mixture to separate the precipitate, evaporating the precipitate at room temperature for recovering the DHA/EPA in form of crystalline mass, passing the mass through sieve to obtain dry, directly compressible as free flowing powder of free fatty acid DHA/EPA.

- DHA and EPA are isolated using the process of the present invention as free flowing powder form, which is directly compressible.
- Our DHA and EPA, in powder form are free from triglycerides.
- Having purity more than 90 %
- Excellent stability at room temperature

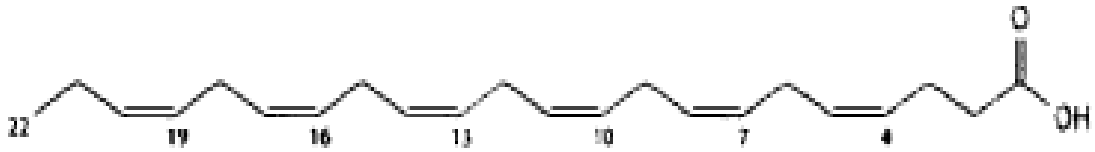
DHA & EPA:

Pure DHA and EPA in free flowing powder form obtained using the proposed method

1. are substantially free from water
2. are directly compressible.
3. are highly compatible and stable in any form of compositions like solid, liquid, powder compositions, tablets, capsules, gels and all other forms of formulations.



EPA



DHA

Characterization and Validation:

DHA (Docosahexaenoic acid) and EPA (Eicosapentaenoic acid) produced using the proposed method are characterized and validated by

1. UV Spectra
2. IR Spectra
3. 13C-NMR Spectra
4. 1H-NMR Spectra and
5. Mass Spectra

Spectral studies have been done in the premier research and educational institutions like Central Drug Research Laboratory, Lucknow, Sophisticated Analytical Instument Laboratory, Punjab, India.

Data confirms that the **isolated constituents in powder form as DHA and EPA**, interpreted and validated by Department of Chemistry, Institute of Science, Nagpur

Studies as Proof of Concept:

Various Studies are conducted on DHA and EPA produced using the proposed method such as

- Preclinical Studies
- Bioavailability Studies
- Stability Testings
- In-Vivo behavioral studies of DHA and
- In-Vivo antiinflammatory studies of EPA

PATENT/IP STATUS

- International Patent App No. PCT/IN2012/000309
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EXPECTATIONS:

- Company seeks to Out-Licenses the Patent Rights on Exclusive or Non-Exclusive Terms.
- Joint ventures, or Sell of patent portfolio.

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