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# Methylcobalamin ICMR Dictates FSSAI: Regulatory Regime in India EXPOSED

Methylcobalamin, an essential nutrient, is required to treat vitamin B12 deficiency, in people with **pernicious anemia, diabetes, and other conditions**. Usually people take such supplement as protective measure. In a country like India where majority of the natives are herbivore, such supplements have become an indispensable element. Methylcobalamin is a step ahead of its sister cyanocobalamin [also a Vitamin B12]. Cyanocobalamin when taken is converted into methylcobalamin leaving a cyanide group which is a toxic component.

## The Methylcobalamin Issue

It is very unfortunate that FSSAI, the only regulating authority of India has approved cyanocobalamin but banned Methylcobalamin **The most important -Vitamin B12**. Surprisingly **methylcobalamin** has been in use for medical purpose in various doses approved by FSSAI. QualPharma is battling since June 2019 against this injustice and is in continuous talks with FSSAI officials and making them under-

stand the importance of Methylcobalamin. **Nutraceutical** is a substance used to prevent disorders and generally referred as health products. Though nutraceutical is for prophylactic cause, still it should be a therapeutic dose. 1mcg of methylcobalamin is of no use as it is too less to prevent any type of disease. A favourable outcome was achieved when we received a letter from former CEO **“Shri Pawan Agrawal Ji”** stating

## Quote

*“Such decisions are taken by FSSAI's Scientific Panel after risk assessment based on secondary data and then goes through a process of approval through Scientific Committee, Food Authority and the Ministry of Health.*

*Good news is that Methylcobalamin (Vitamin B12) has been okayed by the Scientific Panel. However, for this to come into effect it has to go through a process, hence will take sometime.*

*We will try and expedite it as much as possible.”*

## Unquote

FSSAI made the condition worse by mentioning the RDA value of methylcobalamin as 1 mcg which is lower than 2.4 mcg specified by USFDA for the United States where the natives are non vegetarian. As per Section 22 of FSS Act, 2006 and Nutraceutical regulations health supplements or nutraceuticals shall contain minerals or vitamins only in amounts not exceeding the Recommended Daily Allowance (RDA) for Indians. Hence, as per the said Act and Regulations, these products can contain vitamins or minerals only up to its RDA. The Food Business Operator (FBO) who wants to manufacture, import, market or sell such products shall comply with the aforementioned regulations. **Ignoring that RDA and per serving usage are different FSSAI is adamant to enforce 1mcg** as per serving usage value by the manufacture.



**Dr Sanjay Agrawal**

Dr Sanjay Agrawal founded PHARMA CONSULTANTS and INVENTOR in 2005 to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years. He is Editor-in-Chief of renowned IJM Today and honorable member of the editorial board of QualPharma and The Antiseptic. Dr Sanjay Agrawal is also the illustrious member of the National Geographic Society and ex- member of scientific committee of IDMA. His prestigious articles are published in various magazines and websites for example—The Antiseptic, NuFFooDS Spectrum, Pharma biz

Dr. Agrawal had received various awards for his valuable support and contributions in Healthcare and pharmaceutical sector .Dr. Agrawal obtained his postgraduation in Biochemistry from prestigious institution, completed MBBS and MBA from IMT. He has worked with many International and national Pharmaceuticals company. Dr. Sanjay Agrawal is the patent holder of many research formulations which are successfully commercialized

Currently besides his core jobs, Dr Agrawal devotes his time for the benefit of pharma fraternity. He has raised his voice against the ban imposed on methylcobalamin manufacturing. He has been asking to the regulators from more than a year that

- Why Methylcobalamin is not added in the gazette yet when promised by the former CEO Mr Pawan Agrawal Ji?
- Why cyanocobalamin is promoted even though there is a cyanide group attached to it?
- Why 1 mcg RDA is imposed on nutraceutical manufacturer
- Technical aspect of damage caused when 500 mcg is taken as prophylactic use.

These doses of 1 mcg methylcobalamin are far beyond the therapeutic value.

### **Methylcobalamin Vs Cyanocobalamin**

When methylcobalamin is consumed it is directly absorbed whereas when cyanocobalamin is consumed, only one tenth of its part is converted into methylcobalamin and absorbed by the body. So, if 1 mcg methylcobalamin is taken, the body will react differently as compared to 1mcg of cyanocobalamin. When 1mcg of cyanocobalamin is taken, one tenth of it is converted to methylcobalamin and absorbed by the body. **But in this case both Cyanocobalamin and Methylcobalamin are having RDA /per usage serving value as 1 mcg.**

### **Methylcobalamin safety profile**

#### **Evidence 1**

A randomized, open labeled study comparing the serum levels of cobalamin after three doses of 500 mcg vs. a single dose methylcobalamin of 1500 mcg in patients with peripheral neuropathy [This study include healthy patients also on which prophylactic study is conducted.]. Conclusion of this study shows that The 500 µg methylcobalamin thrice weekly regime is more effective in increasing the serum cobalamin levels as compared to the 1500 µg methylcobalamin once weekly regime. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6037815/>

#### **Evidence 2**

Study of Dr. Schweikart on Vitamin B 12 concluded that in dietary supplement for *prevention and maintenance doses*. The aim is to cover the daily requirement and to keep the B12 supply stable.

**Recommended dose:** depending on the individual between 10 – 1000 µg/day. <https://www.b12-vitamin.com/dosages/>

#### **Evidence 3**

Dr. Schweikart again states There are different factors which increase the vitamin B12 requirement. Among the most important are: Pregnancy and lactation/ Exposure to toxins and radicals/Stress/ Athletic sport/Infections and malabsorption due to Old age /Inflammation of

the stomach, intestines and/or pancreas/Intestinal surgery/ Interactions with medicines or drugs/Nutrient deficiencies (e.g. calcium)/Fungal, parasite or bacterial infections in the intestine. With age, the absorption ability decreases. Therefore, B12 markers do not completely normalise in older people unless daily doses between 500-600 µg or more are administered. This is an average value and in individual cases significantly higher doses may be necessary, which is why a dose of 1000 µg has also proven to be effective here.<https://www.b12-vitamin.com/high-dose/>

#### **Evidence 4**

In a review article *Review Article Austin J Pharmacol Ther. 2015; 3 (3).1076. It is mentioned that For daily stress relief, methylcobalamin should should be taken in the dose of 500 mcg per day. In the acute cases of neuropathy, dose of 1500 mcg per day can be safely taken. Dose of 1 mg per day is required to be taken for age related brain decay. Methylcobalamin can be combined with similar dose of folic acid and pyridoxine [20]. Deficiency of vitamin B<sub>12</sub> is strictly seen in pure vegetarian, dose of 100 mg day can rebalance its requirement in the intestine. All human being need at least 3 mg per day of this drug for the basic nerve support. The medicine is stored in the refrigerator below 41°F (5°C) to avoid moisture. Methylcobalamin is also injected deep in to the muscles.* <https://austinpublishinggroup.com/pharmacology-therapeutics/fulltext/ajpt-v3-id1076.php>

#### **Evidence 5**

The dose of methylcobalamin can vary depending on what you are specifically treating. For fatigue conditions it is common to take 1-2 mg daily either subcutaneously or via nasal spray, however lozenges are also available. <https://custommedicine.com.au/health-articles/methylcobalamin-vitamin-b12/>

#### **Evidence 6**

The absorption of vitamin B12 mediated by the glycoprotein, intrinsic factor, is limited to 1.5–2.0mg per meal because of the limited capacity of the receptors. In addition, between 1% and 3% of any particular oral administration of vitamin B12 is absorbed by passive diffusion. Thus, if 1000mg vitamin B12 (sometimes used to treat those with PA) is taken orally, the amount absorbed would be 2.0mg by active absorption plus up to about 30 mg by passive diffusion. Intake of 1000mg vitamin B12 has never been reported to have any side-effects (8). Similar large amounts have been used in some preparations of nutritional supplements without apparent ill effects.

<https://apps.who.int/iris/bitstream/handle/10665/42716/9241546123.pdf;jsessionid=7EA2C12295BA7D9DA9FDF7E1B8965998?sequence=1>

#### **Vitamin C Issue**

Methylcobalamin is not an exception, if we talk about Vitamin C honorable prime Minister Narendra Modi encouraged usage of 1000 mg Vitamin C as prophylactic dose to protect oneself from Coronavirus. Whereas FSSAI has 40 mg as its RDA which is in opposition to Mr. Prime Minister's statement. When asking for clarification QualPharma was informed to contact ICMR. As the RDA for different essential nutrients for Indians are specified by Indian Council of Medical Research (ICMR) which also specified RDA for vitamin B12 (irrespective of its sources such as methylcobalamin or cyanocobalamin) as 1 mcg.

#### **FSSAI Official Quotes**

“The notification dated 7th January, 2020 mentions the same. Since revision of RDA does not fall under the scope of FSSAI and any such request may be taken up with ICMR rather than with FSSAI.”

**METHYLCOBALAMIN – 1MCG**  
**Vitamin C– 40 mg**  
**Is it enough for prophylactic use?**

**What is ICMR**

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world.

The ICMR has always attempted to address itself to the growing demands of scientific advances in biomedical research on the one hand, and to the need of finding practical solutions to the health problems of the country, on the other. The ICMR has come a long way from the days when it was known as the IRFA, but the Council is conscious of the fact that it still has miles to go in pursuit of scientific achievements as well as health target.

**What is FSSAI**

Food Safety and Standards Authority of India is an autonomous body established under the Ministry of Health & Family Welfare, Government of India. The FSSAI has been established under the Food Safety and Standards Act, 2006, which is a consolidating statute related to food safety and regulation in India.

## METHYLCOBALAMIN – 1MCG Vitamin C– 40 mg Is it enough for prophylactic use?

FSSAI is preparing regulations for the nutraceutical industry, therefore the QualPharma has approached FSSAI to share the rationals to decide RDA for which QualPharma is fighting for justice for which we received completely in appropriate response from FSSAI consultant N Bhaskar who blamed us to pressurize FSSAI.

Our last 1 year of contact with FSSAI was horribly flawed leading us to think that FSSAI has become political body not the scientific body misleading to the industry.

- Why Methylcobalamin is not added in the gazette yet when promised by the former CEO Mr Pawan Agrawal Ji?
- Why cyanocobalamin is promoted even though there is a cyanide group attached to it?

- QualPharma is asking for rationality why 1 mcg RDA is imposed on nutraceutical manufacturer

- Technical aspect of damage caused when 500 mcg is taken as prophylactic use.

And last but not the least

- Why should we have faith in FSSAI when every time we have to go to ICMR for clarification.

~By Dr Sanjay Agrawal

*For any clarification or suggestions, readers may contact with QualPharma technical team.*

**IMPORTANCE OF METHYLCOBALAMIN**

Methylcobalamin is a naturally occurring form of vitamin B12 which can be obtained through supplements, as well as food sources like fish, meat, eggs and milk. Methylcobalamin is better utilized and is direct active form. It is a cofactor for the cytosolic methionine synthase. It is needed for the function of the folate-dependent enzyme and methionine synthase. This enzyme is required for the synthesis of methionine from homocysteine. Methionine in turn is needed for the synthesis of S-adenosylmethionine, a methyl group donor employed in several biological methylation reactions, including the methylation of a number of sites within DNA, RNA, and proteins. Inadequate function of methionine synthase can lead to an accumulation of homocysteine, which has been associated with

increased risk of cardiovascular and neuropsychiatric disorders. Methylcobalamin due to its high plasma protein binding capacity is accumulated and retained in the body much better than cyanocobalamin therefore the retention time is more. In any form, methylcobalamin has higher bioavailability than cyanocobalamin. It is so efficient that even orally it was found effective in pernicious anemia – a disease with deficiency of red blood cells.

Methylcobalamin shows its greatest utility with people suffering from acute or chronic degenerative neurological symptoms, here it is considered as the only promising treatment available. It bypasses several potential issues in the absorption cycle and helps relieve or

completely reverse symptoms

Majority that is 99% of people in the world are in need of extra vitamin B12, and Methylcobalamin would be considered as a better option compared to cyanocobalamin. It exhibits many neuro protective effects, improving brain cognition back to normal levels. Plus, Methylcobalamin is donating an extremely valuable methyl group that further enhances our health (and doesn't steal any, like cyanocobalamin does). This is especially important for pernicious anemia patients or anyone suffering from high homocysteine levels. This donation of methyl groups may be the reason why Methylcobalamin is helpful to multiple conditions.