

# QualPharma

FSSAI approved

**Dietary Supplements  
of Methylcobalamin**

available in much higher  
concentration than specified RDA

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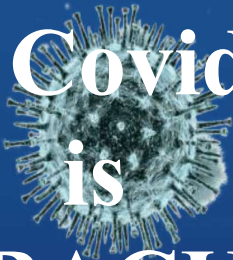
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# FSSAI approved Dietary Supplements of Methylcobalamin available in much higher concentration than specified RDA

Methylcobalamin has become the hot topic of the year. In this ongoing pandemic when enhancing the immunity and strength has become the priority of most of the individual's, FSSAI is making a joke of such an important micronutrient. There are two important questions running parallelly.

1. Whether Methylcobalamin is approved by FSSAI?
2. If yes, is the 1 mcg RDA decided by the FSSAI for the healthy individual also applicable for dietary supplements manufacturer.

## Whether Methylcobalamin is approved by FSSAI?

As per Food Safety and Standards Act 2006 regarding operationalisation of standards of Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel food only cyanocobalamin and hydroxycobalamin

are approved despite former CEO Mr. Pawan Agrawal confirming to QualPharma in December 2019 that methylcobalamin is approved by the scientific committee and soon will be included in the gazette. There are thousands of methylcobalamin brands available in the market which are approved by the authority raising a big question on the Food Regulatory Authority. The FSSAI version has not yet come out even with many scientific evidences have been submitted which shows methylcobalamin as an important nutraceutical for the Indian public. Not only in India methylcobalamin is approved in whole world.

## RDA Status

Questions have been raised time and again about the ambiguous RDA value and TUL of methylcobalamin which till today Food Safety and Standards Authority of India (FSSAI) is unclear about and has been taking refuge of Indian Council

of Medical Research (ICMR) due to lack of scientific evidence. Until and unless, FSSAI does not inform the industry that methylcobalamin is approved, there is no meaning of prescribing RDA value for the same. Surprisingly the mails which we have received from FSSAI on methylcobalamin and cyanocobalamin, both have the same RDA value for manufacturing. The issue has been festering due to missing exact information on tolerable upper limit (TUL) of vitamin B12 [methylcobalamin to be specific] from the public domain. No adverse effect has been associated with excess methylcobalamin intake from food or supplements in healthy individuals. Methylcobalamin has a history of safe long term use as a therapeutic agent given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption.



### 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, Pharmabiz

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

Methylcobalamin is an essential nutrient and is required to treat vitamin B12 deficiency, in people with pernicious anaemia, diabetes and other conditions as well. It is important for the brain, nerves and for the production of red blood cells (RBCs). FSSAI and CDSCO have been drawing flak from the industry as there is no clarity on TUL and RDA values of many micronutrients including vitamin C and methylcobalamin. Unmindful of the concerns regarding RDA for mental health conditions and neurological disorders, industry has dubbed FSSAI as white elephant and urged the Centre that there is no need of FSSAI as the authority is not competent enough to talk on technical and scientific aspects and only relies on the dictates of ICMR. It is a sheer wastage of public money which has been pooled in to maintain an authority which is doing more harm than good.

### Who should regulate Nutraceuticals

The status of Nutraceutical in Indian Drugs Regulatory system has been a point of debate for nearly a decade now. The industry and regulatory bodies were well aware of the situation that the prevailing law of FSSAI is not doing justice to Nutraceutical manufacturers. Strangely, the industry instead of pressing for a legal status found it convenient to take a stand that Nutraceuticals were out of the purview of the Drugs and Cosmetics Act and hence could be manufactured and sold without drug license.

The definition of drug in the Drugs and Cosmetics Act is wide enough to cover any substance manufactured for sale under any of the purposes stated there in and the sales promotion methods and claims for most of the products leave no option but to deem them as drug.

According to Drugs and Cosmetic Act

the definition of Drug is “ All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.”

Therefore, Nutraceuticals which are used for prevention of the disease must be handles by DCGI as they are more technical compared to FSSAI .

Before 2006, the nutraceuticals was handled by DCGI only. A vitamin combination in therapeutic/ prophylactic dosage form cannot be deemed as food supplement. A layman's understanding of a drug and food is very clear. A food or food supplement is one, which you take as you please as in the case of Horlicks or Complan while most of the other so called food supplement claimed multivitamin - mineral combinations are not and a drug is one advocated by physicians for specific purposes. Surely the so-called Nutraceuticals do not enjoy any exemption from the Drugs and Cosmetics Act and as such they are drugs and are well regulated.

### Conclusion

- **FSSAI must clarify whether methylcobalamin is approved or not and if not then Why?**
- **Why so many methylcobalamin brands are available over**

## RDA specified by FSSAI IS 1 mcg

**Some of the widely sold brands approved by FSSAI and available in the drug retail supply chain are**

- **Organic B12 500 mg**
- **Health Aid Vitamin B12 (methylcobalamin) 1500 mcg,**
- **Nature Made Vitamin B12-1000 mcg,**
- **B-12 dots by Twinlab-500 mcg,**
- **Jarrow Formulas, Methyl B-12-1000 mcg,**
- **Nature's Bounty Vitamin B-121000 mcg**
- **Source naturals methylcobalamin Vitamin B12-5000 mcg,**
- **solgar sublingual methylcobalamin supplement-1000 mcg,**
- **Cobaforte CD3 plus tablet-1500 mcg,**
- **Nocob methylcobalamin 1500mcg,**
- **Unived methylcobalamin 1500mcg,**
- **Bhumija Lifesciences vitamin B12 1500 mcg,**
- **Bluebonnet liquid methylcobalamin - vitamin B12 1000 mcg,**
- **EZ Melts B12 as methylcobalamin, 2,500 mcg and**
- **Garden of Life Vitamin Code vitamin B12-1000 mcg**

**the counter?**

- **Why RDA is enforced on the manufacturers.**
- **And if 1 mcg is the RDA why so many brands are approved by FSSAI upto 500 mg.**

~By Dr Sanjay Agrawal