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for ailing*

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Post Covid-19

*Critical Quality Measures for
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AND MORTAR PHARMACIST**
Online war for Battle of survival

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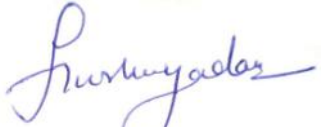
FROM THE DESK OF EDITOR - IN - CHIEF

Dear Readers,

Pharmaceutical experts is fighting for more than a year to release the gazette approving methylcobalamin. So far the regulators had approved only hydroxycobalamin and cyanocobalamin which is an inferior B12 as compared to methylcobalamin. The former CEO Pawan Agrawal had promised in December 2019 that methycobalamin has been approved by scientific committee and will take the due course of its time to be included in the gazette. Nevertheless the Pharma experts has waited for almost a year without any progress for inclusion of the product in the gazette. QualPharma support the pharma experts opinion.

Coming back to our edition we have Bodh Raj Sikri **Key Promoter of ABS Group on our cover page**. You may keep yourself updated on **Corona stories, medical and marketing articles and zodiac prediction from our expert**.

You may know more about us through <http://www.qualpharma.in/>. **STAY UPDATED STAY BLESSED** and do not forget to follow up our blog <https://qual-pharma.blogspot.in/> to receive regular interesting updates.



(ANSHU YADAV)

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STAY HOME

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Pharmaceutical experts wants right prescription for ailing FSSAI

Our Fight Continues

Methylcobalamin is an essential nutrient and is required to treat vitamin B12 deficiency, in people with pernicious anemia, diabetes and other conditions as well. It is important for the brain, nerves and for the production of red blood cells (RBCs).

Pharmaceutical experts is fighting for more than a year to release the gazette approving methylcobalamin. So far the regulators had approved only hydroxycobalamin and cyanocobalamin which is an inferior B12 as compared to methylcobalamin. The former CEO Pawan Agrawal had promised in December 2019 that methylcobalamin has been approved by scientific committee and will take the due course of its time to be included in the gazette. Nevertheless the Pharma experts has waited for almost a year without any progress for inclusion of the product in the gazette.

Alarmed and infuriated at the ongoing raids on methylcobalamin, manufacturers and industry has

raked up methylcobalamin ban issue terming it as an extortion bid by state drug controllers (SDCs) in name of regulation.

FSSAI has been drawing flak from the Pharma experts as ban on methylcobalamin has become a contentious issue today. There is no clarity on tolerable upper limit (TUL) and RDA value.

According to an Pharma expert, "The dual standards of FSSAI can be seen by the presence of already FSSAI approved brands available with 1500 mcg qty/per serving. **Rejunex CD3 of Intas is a FSSAI approved product containing 1500 mcg Methylcobalamin. Some of the widely sold brands are Locopen capsule, Neugaba M 75 capsule, Nervup 500 mcg injection, Nuroz Forte, Nurofine-2500 injection, Actavis 2500 injection, etc. There are more than half a dozen other brands with the same formula.**



Dr Sanjay Agrawal

Dr Agrawal has actively worked in pharmaceutical and related industries for more than 35 years and started this firm Pharmaceutical Consultants and Inventor in 2005. He is **Editor-in-Chief** of renowned IJM Today . Dr Sanjay Agrawal is the illustrious member of the National Geographic Society and ex-member of scientific committee of IDMA. He 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. He has worked with many International and national Pharmaceuticals companies. Dr. Sanjay Agrawal is the patent holder of at least 40 research formulations.

According to Gujarat FDCA Commissioner Dr H G Koshia, **“There is a ban on methylcobalamin pan-India and the states need to follow it as per FSSAI directive.”**

The Central Drugs Standard Control Organisation (CDSCO) had earlier urged the FSSAI to take action against Gujarat-based manufacturers for manufacture and sale of methylcobalamin meant for therapeutic intervention in contravention of norms. In a letter to the FSSAI, CDSCO has brought to the notice that various brands of product containing methylcobalamin are manufactured and sold having therapeutic intervention under the FSSAI license.

In view of the same, it has been recommended on priority basis to instruct drug inspectors and food safety officers to launch surveillance drives against various brands of products containing me-

thylcobalamin being manufactured and sold under FSSAI license.

Pharma experts have voiced concern that methylcobalamin's RDA value has been approved by Central Drugs Standard Control Organisation (CDSCO) to 2000 mcg but FSSAI is approving only 1 mcg which is of no use. Drugs Controller General of India (DCGI) had approved 2,000 mcg of methylcobalamin even in injectable form and such brands are also available as patients take methylcobalamin based on the medical condition.

Unfortunately due to slow process, though approval nod for Methylcobalamin, yet it is not included in the gazette.

Until and unless FSSAI does not inform the industry that methylcobalamin is approved, there is no value of prescribing RDA value for the same. We have received many emails from the regulators who had referred RDA of methylcobalamin. So it is not clear how regulators are talking about RDA without inclusion of the product in the gazette. Surprisingly in the mails which we have received from FSSAI, methylcobalamin and cyanocobalamin both have the same RDA value to manufacture. Probably FSSAI is confused about the RDA required and per serving usage to be manufactured. We are repeatedly talking about per serving usage value which the manufacturer can refer to and not the RDA value for a healthy person.

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QA & REGULATORY

However, on January 7, 2020, FSSAI issued a notification regarding RDA of vitamin B12 which is specified as 1 mcg without mentioning type of vitamin B12 like methylcobalamin, adenosylcobalamin, hydroxycobalamin and cyanocobalamin.

The hurdles for the nutraceutical manufacturers will not be solved by only inclusion of methylcobalamin in the gazette but also by revising the irrational enforcement of RDA of methylcobalamin.

ICMR and National Institute of Nutrition has issued another report on RDA and estimated average nutrient requirements for Indians 2020 which says a completely different story. According to the report there is limited evidence to suggest a level at which adverse events can be observed. In the Norwegian Vitamin (NORVIT) intervention trial, patients with acute myocardial infarction received 400 µg of B12 daily for 3 years and reported no serious adverse events. In another study (HOPE 2), patients with vascular disease or diabetes aged >55 y received 1 mg B12 daily for 5 years and reported no serious

adverse event with this treatment. Additionally, the IOM (1998) also states that there is no adverse effect associated with excess B12 intake from foods or supplements in healthy individuals.

The ICMR report also says that “there is limited absorption of Vit B12 from gastrointestinal tract with high doses, and therefore, IOM did not establish an upper limit for B12.

The evidence from the limited data is not sufficient for deriving Tolerable Upper Limit (TUL). Further, the Indian population mostly consume vegetarian diets which do not provide B12, except milk and its product. Therefore, high intakes of B12 from foods are unlikely.

Therefore the manufacture must be allowed to produce atleast to the therapeutic dose.

Another document University of Rochester Medical Centre have claimed that **“Your body can't absorb all the vitamin B-12 from dietary supplements. Absorption is limited by**

how much intrinsic factor your stomach makes. Intrinsic factor is needed for your body to absorb B-12. For example, only about 10 mcg of a 500 mcg oral supplement is actually absorbed in healthy people.”

Additionally “Vitamin B-12 deficiencies tend to be caused by not getting enough B-12 in your diet. They can also be due to a reduced secretion or lack of intrinsic factor. This is a stomach secretion that helps the body absorb vitamin B-12.” In such case supplementation is recommended. I am leaving the readers with an open Question **“Is this ban on methylcobalamin by FSSAI really worth?”**

~By Dr Sanjay Agrawal

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

R_x

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CORONAVIRUS SPECIAL

The immune system against COVID 19 is long lasting

Researchers who monitored 185 men and women, aged 19 to 81, who had recovered from Covid-19 found that most still had enough immune cells to prevent illness eight months after the infection.

The new study, which has not been peer-reviewed, involves analyzing multiple compartments of immune memory over time: antibodies, B cells and T cells, among other features of immune mem-

ory. This has been contradictory to the earlier claims which says antibodies for COVID-19 wane fairly soon which is causing re-infection.

The T-cell immunity is a better and more durable marker for this novel virus. If India's vaccination policy, when made, recommends that vaccines may be conserved for priority use for non-immune subjects, then, a rapid T-cell immunity

test, such as the one developed in Cardiff, will be better than antibody tests.

Therefore, developing simple and rapid assays for T-cell immunity should be a priority for Indian scientists to work on, quickly. Those with T-cell immunity may need no vaccine, or only a single dose of a two-dose vaccine regimen.

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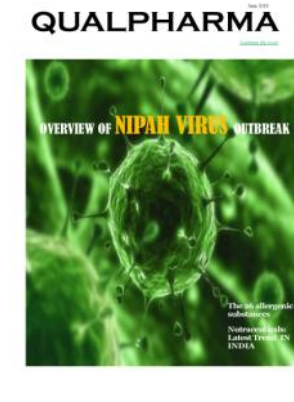
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