A critical analysis on irrational fixed dose combinations of nutraceutical's in India.

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The significance is that these irrational combinations of Vitamins have their own complex effects in the body and many drug-kinetics interactions. These FDCs are freely available and widely consumed by consumers under over the counter in India. The objective of our study to analyze the rationality of Vitamins and minerals combinations available in India.; to provide comprehensive data of irrational combinations having excess and sub sufficient quantity of vitamin and minerals than recommended by Nutrional Guidelines of India. This observational study and analysis was done between April and September 16. Data was collected from current index of medical specialities and drug India. Rationality assessment was done using National list approved drug combinations by Central drug standard control organization (CDSCO) and essentially was cross checked using World Health Organization essential drug list 2015.Adequacy was analysed using Dietary reference intake (DRI). In our analysis, we have found 1184 irrational nutraceutical preparations available in India market. Out of 461(38.9%) are based on fat soluble vitamins, 190(16.4%) based on B-complex vitamins based and 5339(45.1%) related to essential minerals. Among 461 fat soluble vitamins, 104 contain excessive level, 334 contain sub standard levels. Similarly 128 and 62 Vitamin B-Complex based preparations are having excess and less quantity than recommended levels respectively and almost all the mineral combinations except four are not prepared following guidelines. None of these combinations were included in National essential list of medicines. Multivitamins are generally considered safe; these are irrationally prescribed and taken as self medication by public. Many of the ill effects are often unnoticed and under reported. Government of India should regulate the manufacture and sale these nutraceuticals to promote rational use of drugs and to promote well being and safety of Indian population which is primary objective of 'Health for all'.

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2. Gautam CS, Saha L. Fixed dose drug combinations (FDCs): rational or irrational: a view point. British Journal of Clinical Pharmacology. 2008;65(5):795-796. doi:10.1111/j.1365-2125.2007.03089.x.
3. Karelia BN, Buch JG. Analysis of hematinic formulations available in the Indian market. Journal of Pharmacology & Pharmacotherapeutics. 2012;3(1):35-38. doi:10.4103/0976-500X.92504.
4. Rasner F. Shotgun haematinic therapy. Arch Intern Med. 1978;138:1129.
5. Shah A. Iron deficiency anemia - Part III. Indian J Med Sci. 2004;58:214–65.
6. Tripathi KD. 6th ed. New Delhi: Jaypee Brothers Medical Publishers; 2008. Essentials of medical pharmacology; pp. 581–92.



Biography

Dr. Krishnan Vengadaragava Chary: Did his post graduation from prestigious Stanley Medical College . He is an eminent pharmacologist , well known for his teaching skills in college and PG entrance coaching . He has won many prizes including a best poster in IPS conference at Bangalore. He is research coordinator of Saveetha Medical College and consultant for few ethics committee and contract research organization at Chennai. He has five SCOPUS , PUBMED indexed publications. He is reviewer of Science and Engineering Research Board (SERB), Govt of India and in few biomedical journals. He has authored a chapter of Pharmacology in book entitled TARGET JIPMER , 1st ed, 2013 published by Wolters Kluwer