

Nutrient Strength and Dissolution Test Results of Nationally Representative Prescription Prenatal Multivitamin/Mineral (RxP MVM) Supplements

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Objectives: US pregnant women are at risk of dietary deficiencies of iron, folate, calcium and vitamin D and take Rx or non-Rx MVM supplements to optimize their nutritional status. The efficacy of a MVM is determined not only by its ingredient content but also by the ability of tablets and capsules to properly disintegrate and release nutrients. The goals of this Dietary Supplement Ingredient Database study were to measure micronutrients in RxP MVMs and to assess dosage form adherence to the United States Pharmacopeial (USP) dissolution standards.

Methods: Multiple lots of 24 RxP MVMs, representing 61% of the market were tested by commercial laboratories. We compared the content with Recommended Dietary Allowances (RDAs) and Upper Tolerable Intake Levels (ULs). The MVMs were tested for folic acid, iron, riboflavin, and retinol dissolution. To pass, at least 75% of the labeled amount must be released in 1 hour.

Results: The means of daily intakes provided by most RxP MVMs were below 20% RDAs for calcium and magnesium, at about half of the RDA for iodine, at or slightly above RDAs for iron and copper, and almost twice the RDA for zinc. The mean amounts of daily intakes of vitamins A, C, D, E, niacin, and thiamin provided by most MVMs were 70–160%RDAs, although some products contained thiamin, vitamins C or D at 170–240% of RDAs. All MVMs provided amounts of folic acid exceeding the RDA (mean %RDA \pm SD; 334 ± 49). Average measured contents of vitamins and minerals exceeded labeled amounts, including those labeled with amounts above ULs. However, none of the 15 tablet and 4 soft gel products passed dissolution testing for all ingredients required by USP. None of 7 products passed the test for retinol. Only 55% of 11 MVMs in tablets with fast releasing iron sources passed dissolution tests for iron, folic acid and riboflavin. For at least one of those three ingredients, 80–93% of 12–15 tablets passed dissolution, and only 1 of 4 soft gels passed the test with pepsin added to the testing media.

Conclusions: Although RxP MVMs contained several micronutrients significantly exceeding RDAs that might help to close nutrient gaps, the sample of nationally representative RxP MVMs failed to meet all USP standards for ingredient dissolution. This is a concern for pregnant women because nutrients in failed products might not be available for absorption and utilization.

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