SUPPLEMENTAL MATERIAL FOR GAO-24-106689: Testing Results for Selected Prenatal Supplements

Read the full report “Prenatal Supplements: Amounts of Some Key Nutrients Differed from Product Labels. (GAO-24-106689).

GAO-24-107042

December 2023

This supplemental material is a companion to GAO’s report GAO-24-106689 and contains laboratory testing results for the 12 prenatal supplements we selected (presented anonymously as supplement products A through L). We present graphical representations of the measured amount of each tested nutrient relative to the amount of that nutrient stated on the label—called the “percent of the label amount.” We also present a table of laboratory testing results for lots in in which heavy metal contaminants were found in measurable amounts and presents these results in a table because heavy metals were not detected in all samples. For the unprocessed laboratory testing data underlying our analysis, please see the CSV file available for download on the homepage for this supplemental material.

We contracted with an accredited analytical laboratory to conduct blind testing of three different lots of 12 selected prenatal supplement products for six nutrients and four heavy metal contaminants. These 12 products—including five gummies, four softgels, and three tablets—represent different “best-selling” or “top-rated” brands. For a detailed account of the methodology used to select the tested nutrients and heavy metals, as well as how supplement products were selected for testing, see the “How GAO did this study” section of the full report. We purchased three different lots of each supplement product online and in stores for a total of 36 samples. All supplement products were blinded—transferred to nondescript secondary containers—under supervision of an independent witness unaffiliated with our core team, then sent to the laboratory for analysis. All samples—except for the gummies—underwent quantitative testing for all the selected nutrients and heavy metal contaminants. The gummy samples were not tested for iron because iron was absent from their labels.

The results of this testing are limited to the prenatal supplement samples we tested and are not generalizable to the entire universe of prenatal supplements. The results are also limited to the selected nutrients and heavy metal contaminants, so it is unknown whether other contaminants may be present in the selected supplements. Furthermore, officials from the testing laboratory confirmed that all samples were fully dissolved during extraction procedures but were not able to provide a metric for extraction efficiency for their methodology. Therefore, it is possible that low values (or measured percentages less than 100 percent of the label amount) could be due to incomplete extraction or sample deterioration (i.e., vitamin instability). Ultimately, we determined that these tests were suitable for our intended purposes and that the data were sufficiently reliable to report. We did not test the efficacy of the selected prenatal supplements.

We conducted the work upon which this supplemental material is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Contact

Karen L. Howard, Director, Science, Technology Assessment, and Analytics, HowardK@gao.gov, (202) 512-6888

Copyright

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

Contents

Tested Nutrients

The laboratory tested for the amounts of six nutrients—folic acid, iodine, iron, and vitamins A, C and E—in 12 selected prenatal supplements (anonymized as supplement products A through L). The results are organized by nutrient and then by form (gummies, softgels, and tablets). The results are presented as graphical representations of the measured amount of each tested nutrient relative to the amount of that nutrient stated on the label—called the "percent of the label amount." For example, if the measured amount of the nutrient matched the label amount exactly, it would have a value of 100 percent of the label amount. Percentages less than 100 percent mean that the measured amount of the nutrient was less than the amount on the label. Percentages greater than 100 percent mean that the measured amount of the nutrient was greater than the amount on the label. The graphs show these values for each tested nutrient across three lots of the selected prenatal supplements described in our full report (GAO-24-106689).

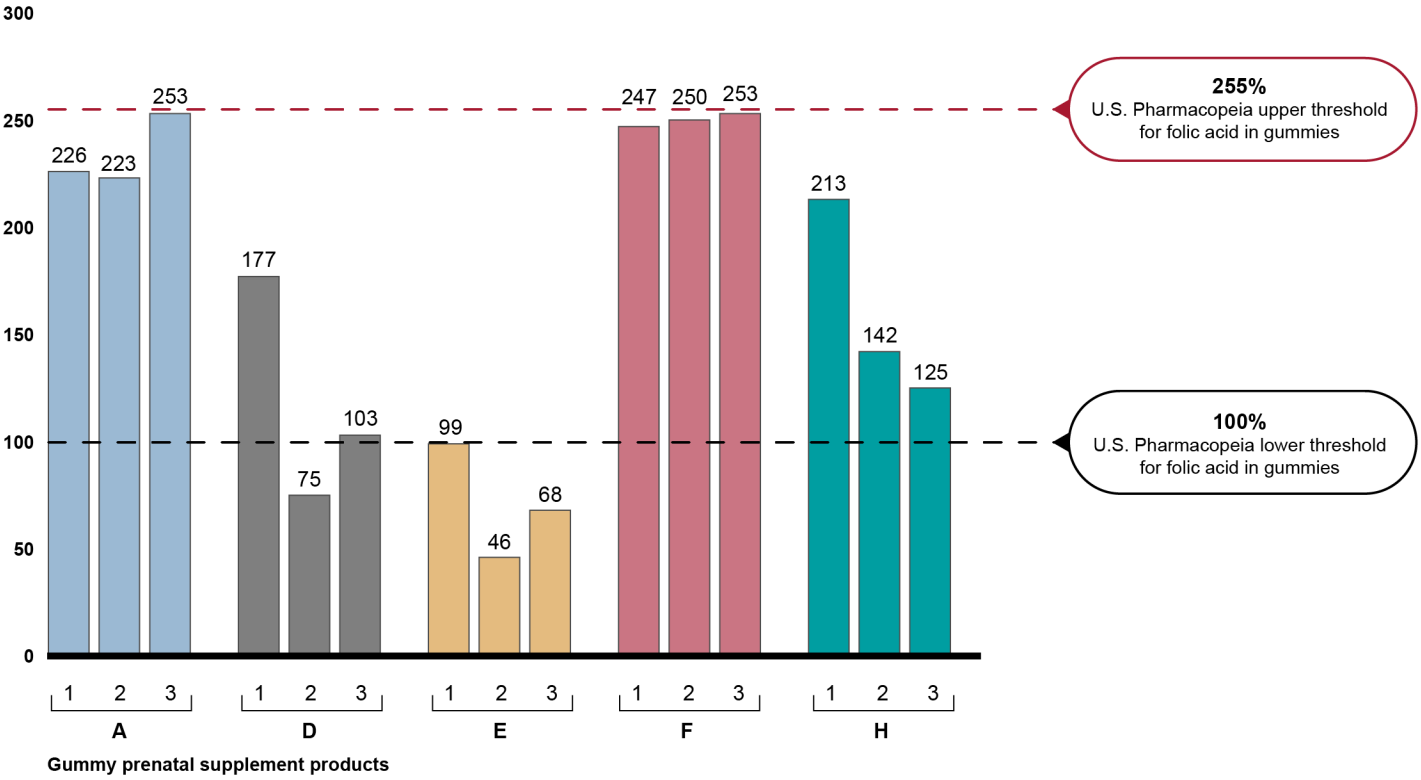
The lower and upper U.S. Pharmacopeia thresholds for acceptable percentages of label amount are also displayed. These U.S. Pharmacopeia thresholds are voluntary manufacturing guidelines for assessing whether the amount of a nutrient stated on the label accurately represents the amount of that nutrient contained in the dietary supplement.[1] Because U.S. Pharmacopeia thresholds are given as percent of the label amount, they are not considered metrics of safety. If the measured amount of a nutrient in a supplement exceeds or falls below the U.S. Pharmacopeia thresholds, that does not necessarily mean the supplement contains unsafe levels of the nutrient.

These figures do not take into account the instrumental or experimental error associated with each individual lot. We anonymized the products with identifiers (i.e., A1, A2, and A3 for the three lots of product A; B1, B2, and B3 for the three lots of product B, and so on) that can be cross-referenced to the unprocessed data in the CSV file available for download on the homepage for this supplemental material.

[1]The Food and Drug Administration (FDA) considers class I nutrients below 100 percent of label amounts to be misbranded, according to FDA officials. In our analysis, we assumed that all tested nutrients in all tested supplements are class I nutrients (added nutrients in fortified or fabricated foods) and not class II nutrients (naturally occurring nutrients). FDA does not have an upper limit for the amount of nutrients permitted in a dietary supplement, and officials stated that FDA examines each product on a case-by-case basis to determine whether the level of nutrient in the product is a safety risk.

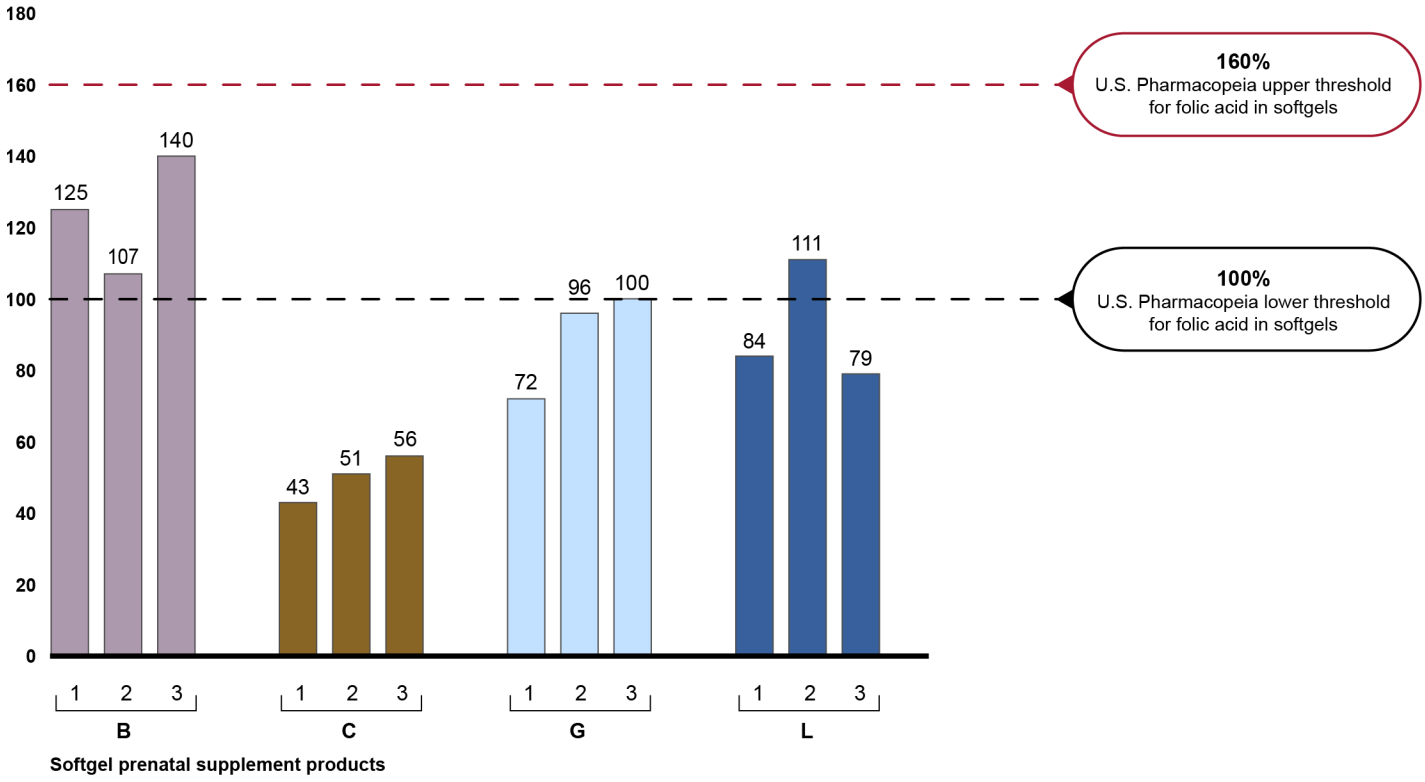
Folic Acid

Figure 1: Measured Amount of Folic Acid as a Percentage of the Label Amount for Three Lots of Each Gummy Prenatal Supplement Tested



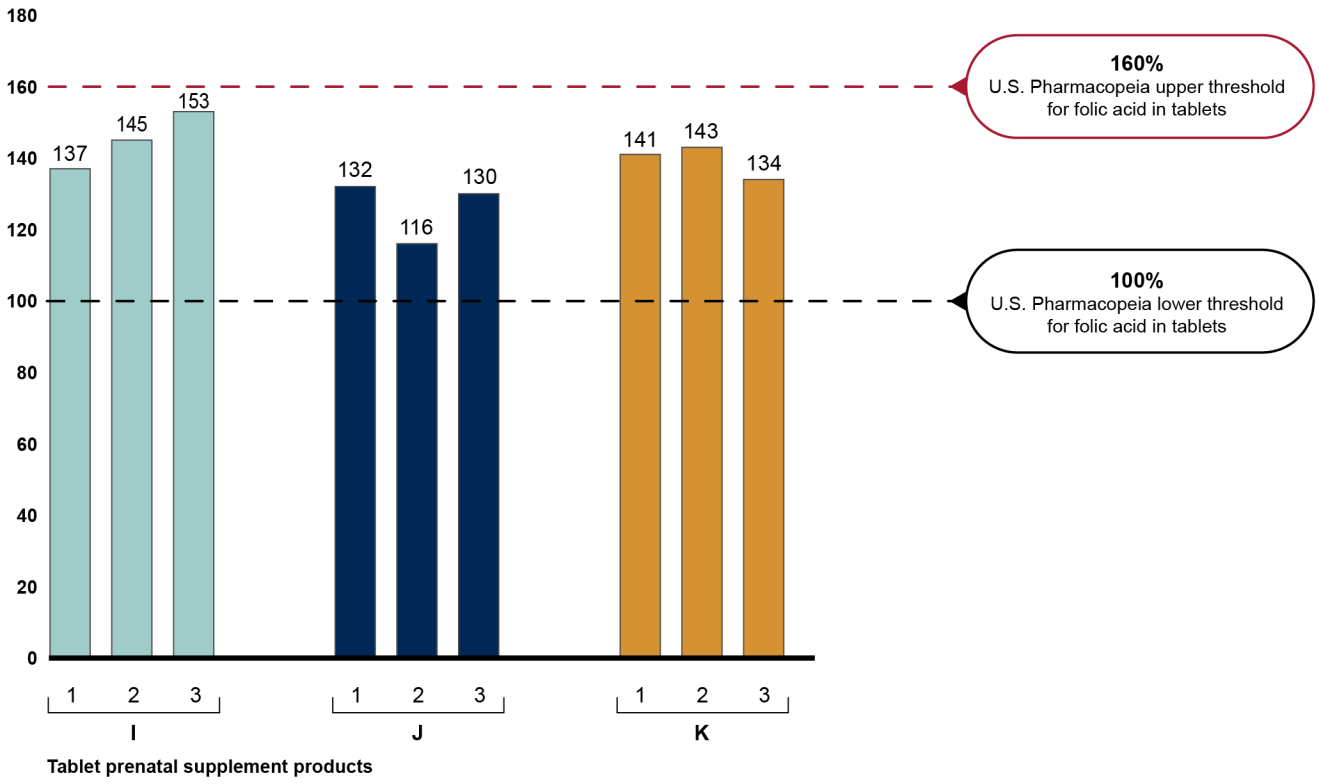
Source: GAO. | GAO-24-107042

Figure 2: Measured Amount of Folic Acid as a Percentage of the Label Amount for Three Lots of Each Softgel Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

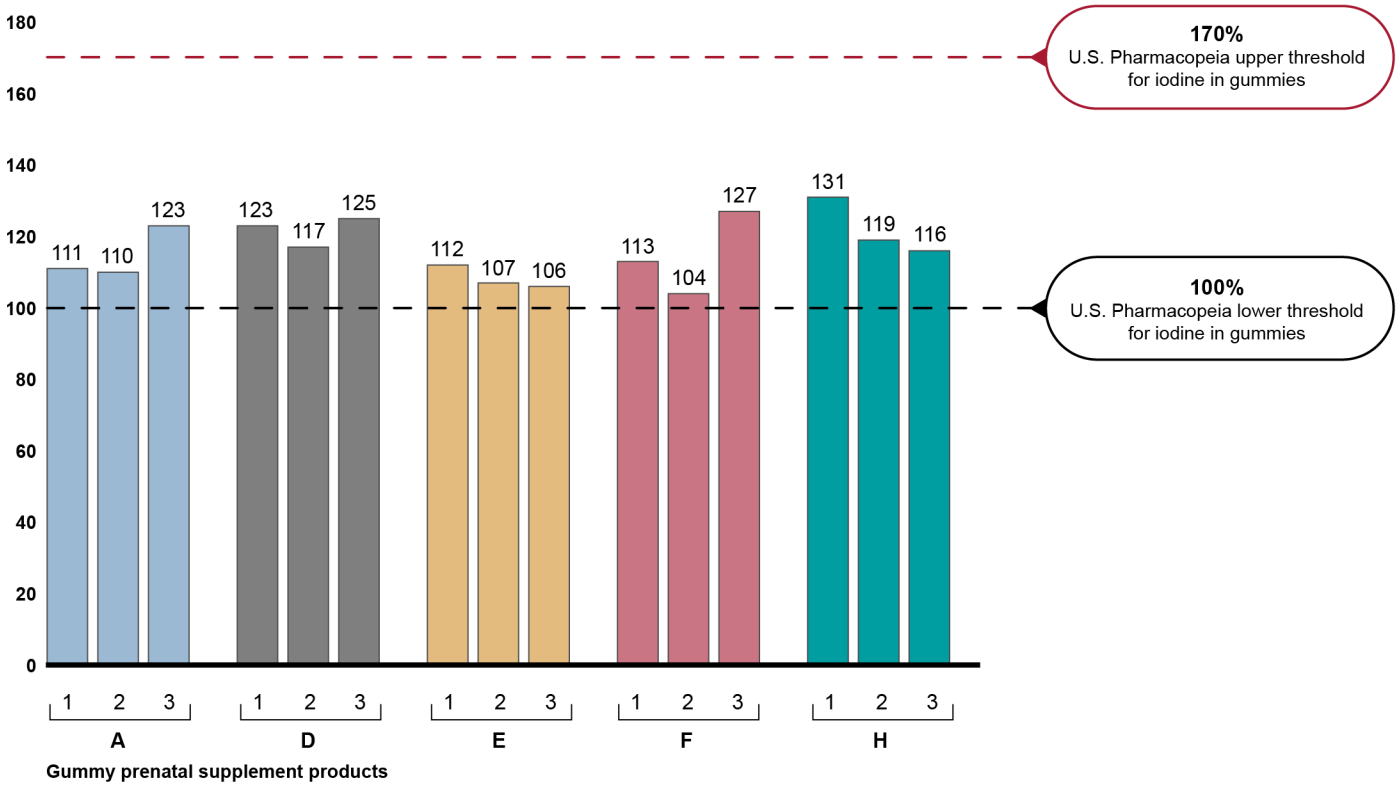
Figure 3: Measured Amount of Folic Acid as a Percentage of the Label Amount for Three Lots of Each Tablet Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

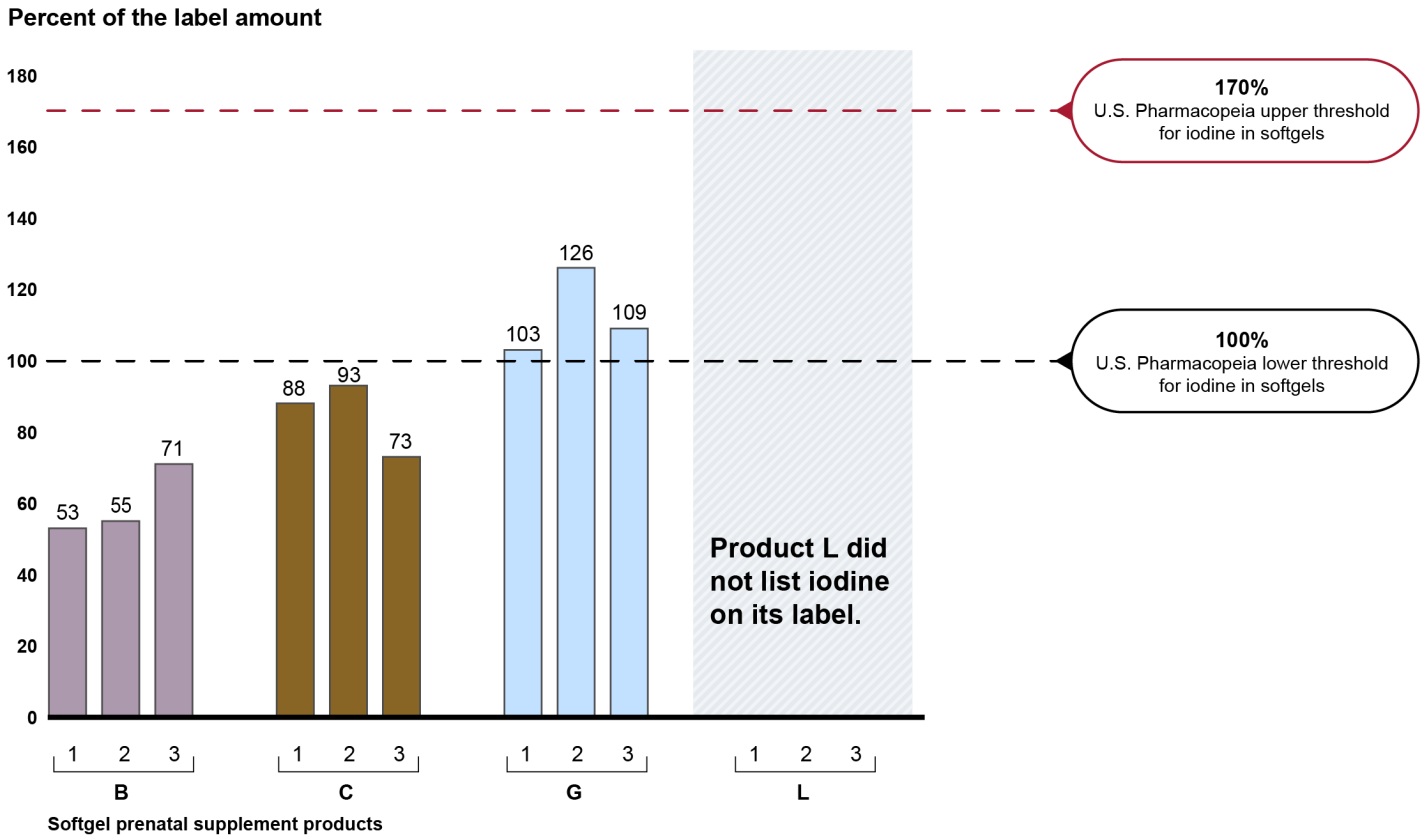
Iodine

Figure 4: Measured Amount of Iodine as a Percentage of the Label Amount for Three Lots of Each Gummy Prenatal Supplement Tested



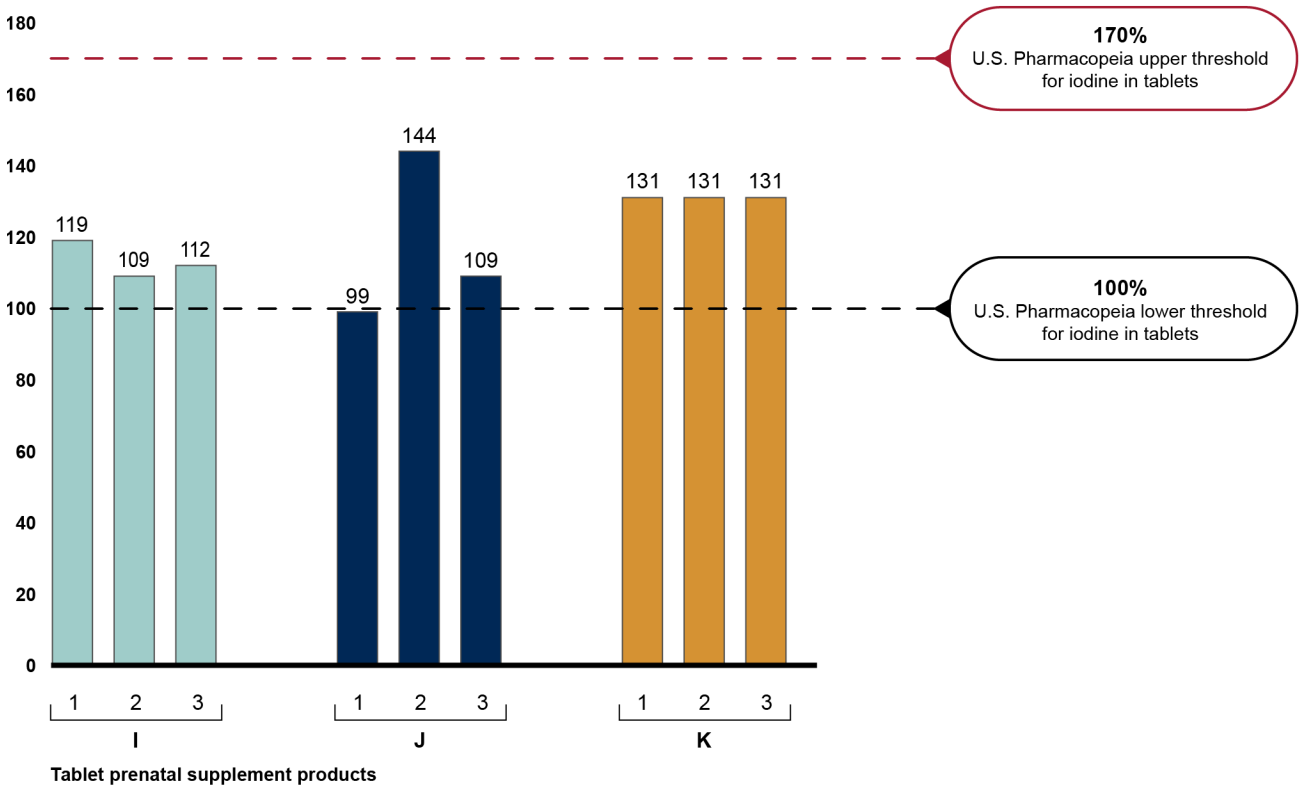
Source: GAO. | GAO-24-107042

Figure 5: Measured Amount of Iodine as a Percentage of the Label Amount for Three Lots of Each Softgel Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

Figure 6: Measured Amount of Iodine as a Percentage of the Label Amount for Three Lots of Each Tablet Prenatal Supplement Tested

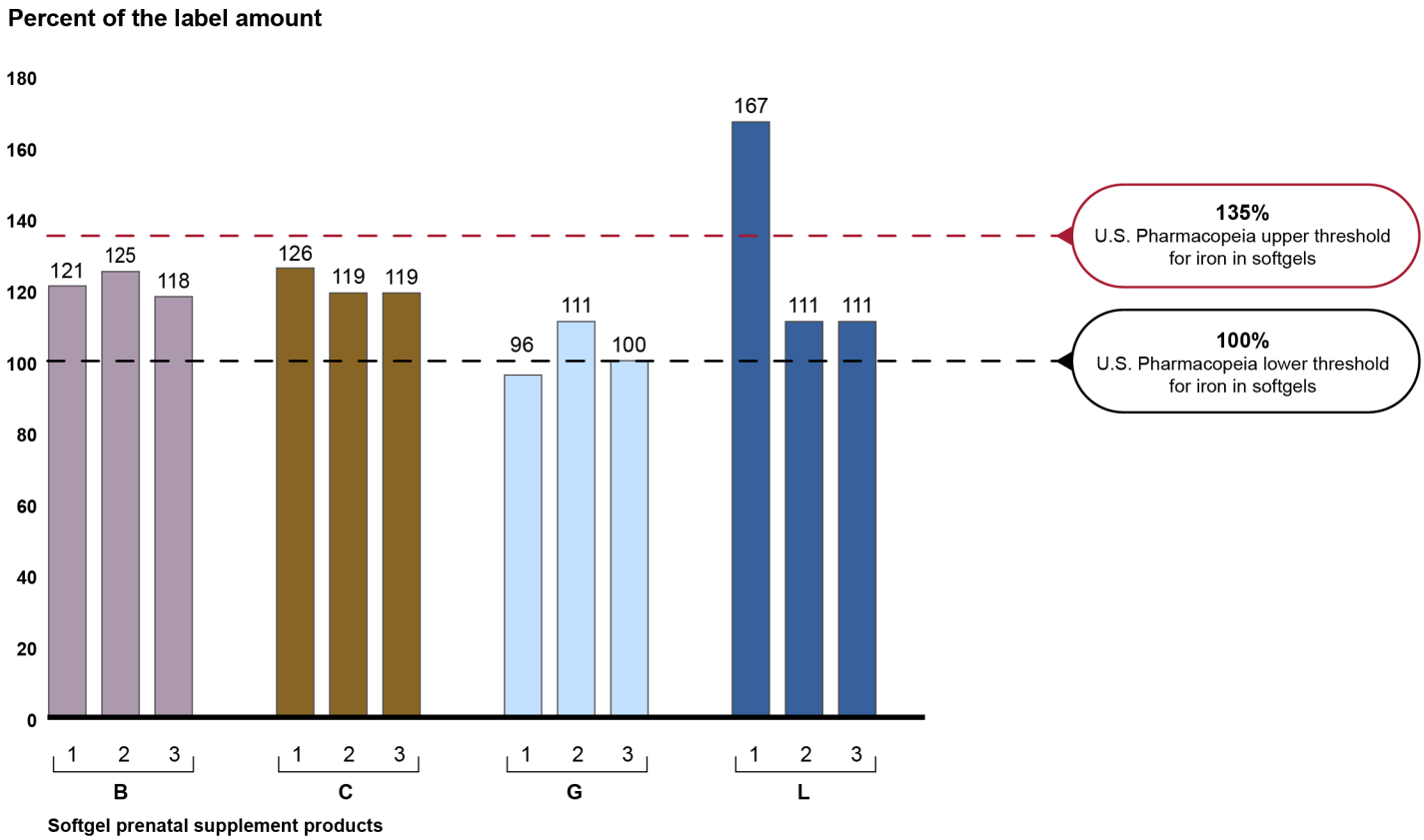


Source: GAO. | GAO-24-107042

Iron

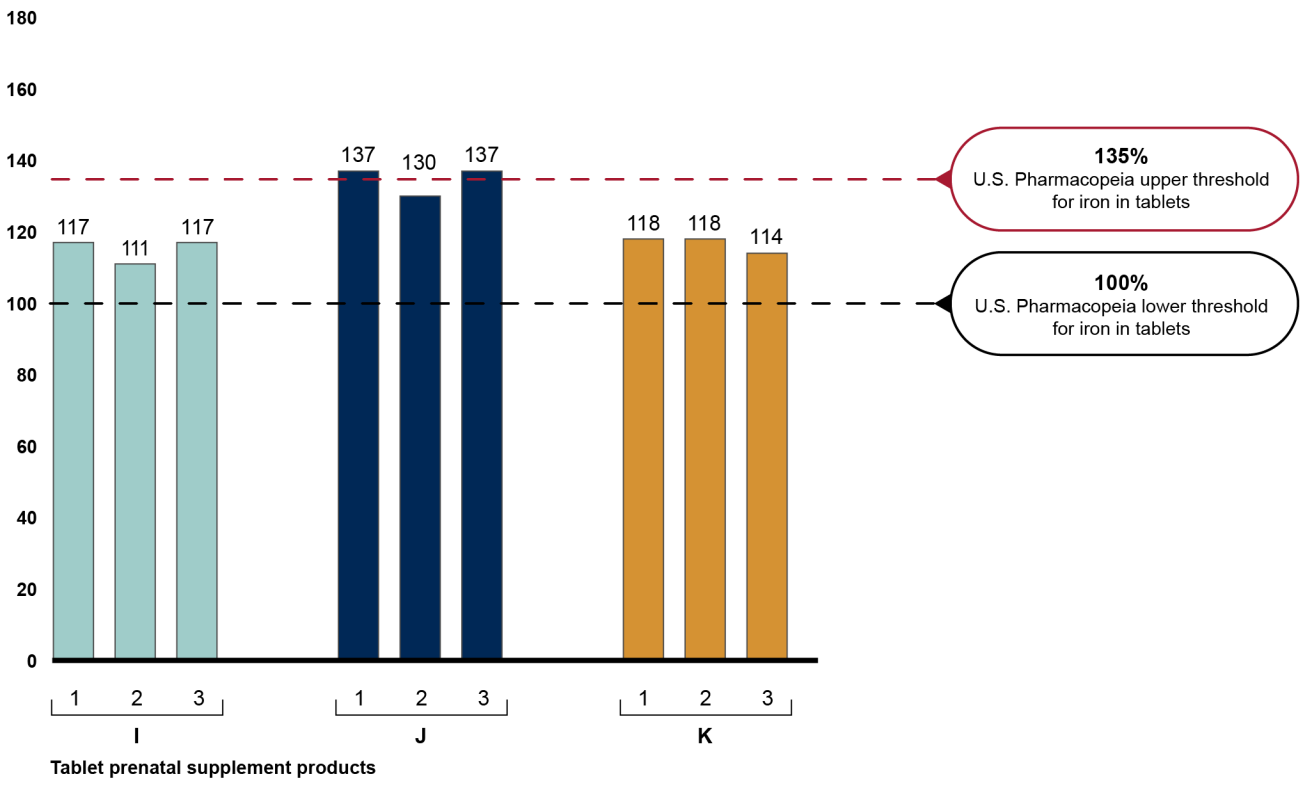
Because none of the tested gummies listed iron as an ingredient on their labels, we did not ask the contracted laboratory to test for that nutrient.

Figure 7: Measured Amount of Iron as a Percentage of the Label Amount for Three Lots of Each Softgel Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

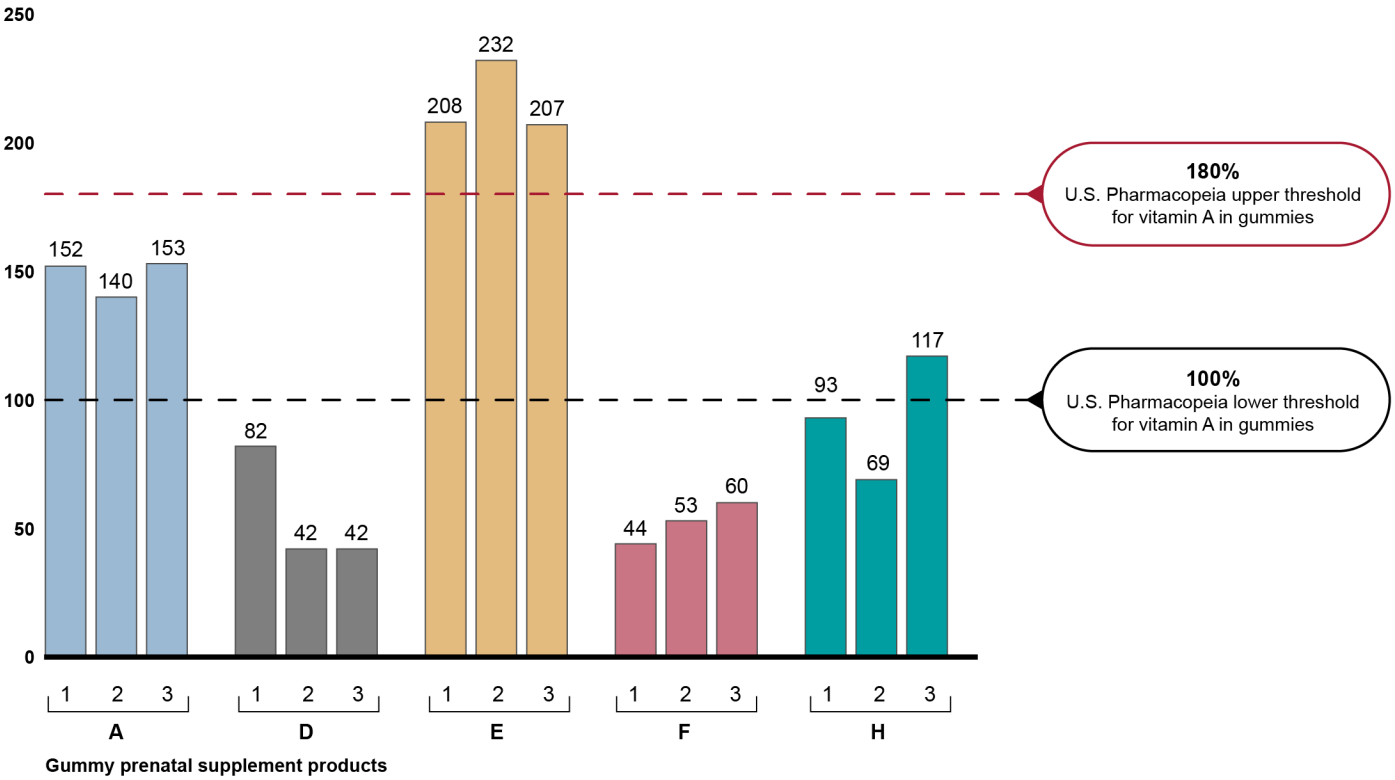
Figure 8: Measured Amount of Iron as a Percentage of the Label Amount for Three Lots of Each Tablet Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

Vitamin A

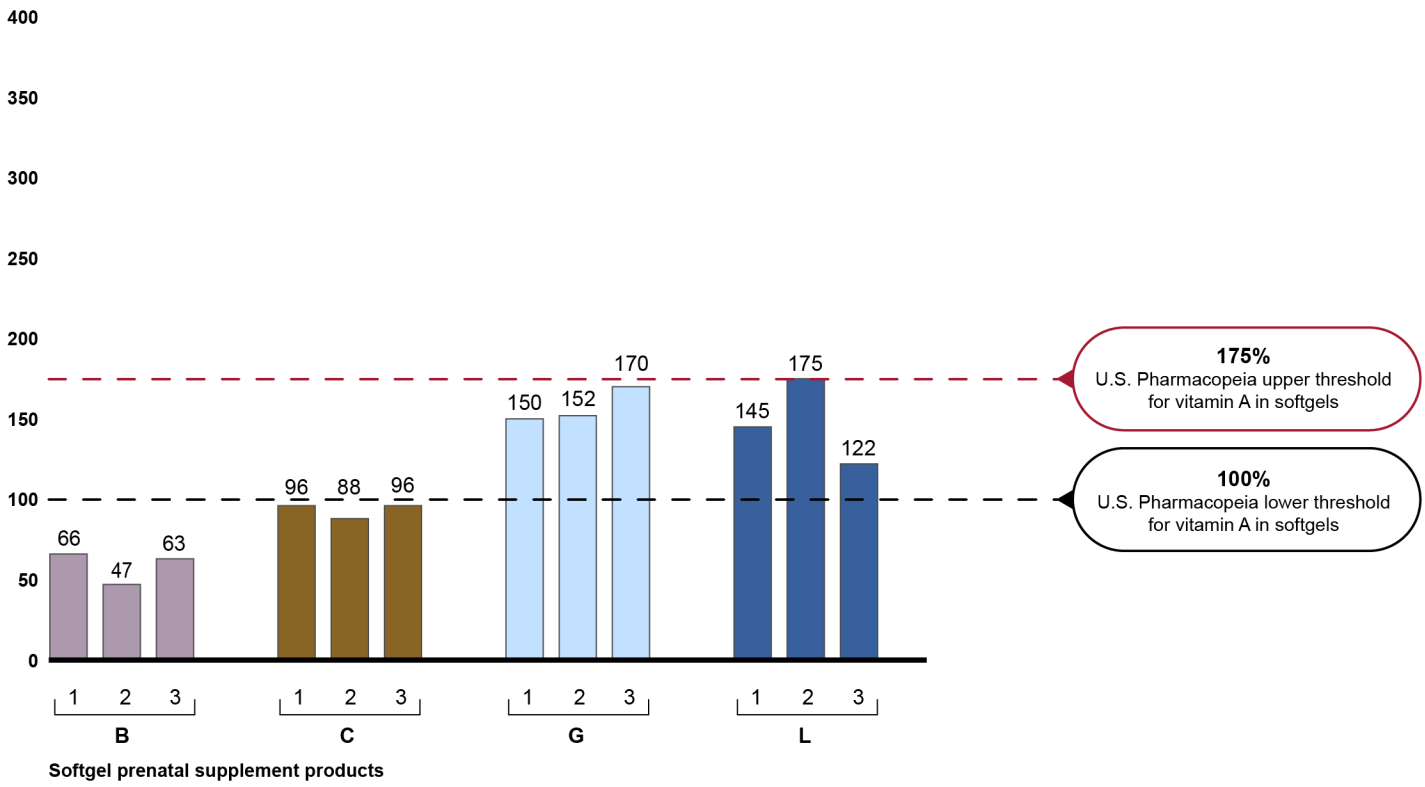
Figure 9: Measured Amount of Vitamin A as a Percentage of the Label Amount for Three Lots of Each Gummy Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

Note: Vitamin A can be present in prenatal supplements in two forms: pre-formed vitamin A (e.g., retinol or retinyl palmitate) and pro-vitamin A carotenoids (e.g., beta-carotene). While only pre-formed vitamin A is associated with toxic effects at high doses, carotenoids alone are insufficient to maintain normal levels of vitamin A. Products A, D, E, and H are 100 percent pre-formed vitamin A (retinyl palmitate or retinyl acetate). Product F is 50 percent pre-formed vitamin A (retinyl palmitate) and 50 percent provitamin A (beta-carotene).

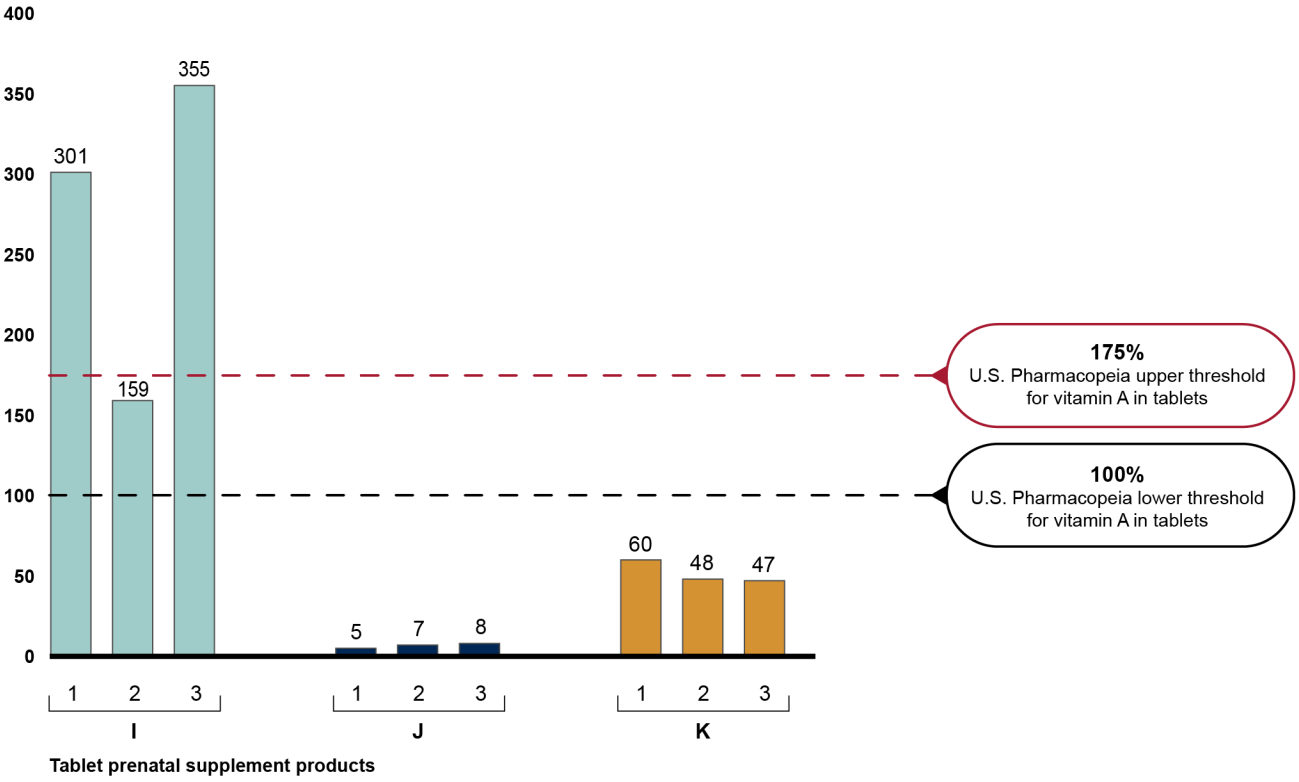
Figure 10: Measured Amount of Vitamin A as a Percentage of the Label Amount for Three Lots of Each Softgel Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

Note: Vitamin A can be present in prenatal supplements in two forms: pre-formed vitamin A (e.g., retinol or retinyl palmitate) and pro-vitamin A carotenoids (e.g., beta-carotene). While only pre-formed vitamin A is associated with toxic effects at high doses, carotenoids alone are insufficient to maintain normal levels of vitamin A. Product B is 50 percent pre-formed vitamin A (retinyl palmitate) and 50 percent provitamin A (beta-carotene). Products C and G are 100 percent provitamin A (beta-carotene). Product L is 100 percent pre-formed vitamin A (retinyl palmitate).

Figure 11: Measured Amount of Vitamin A as a Percentage of the Label Amount for Three Lots of Each Tablet Prenatal Supplement Tested

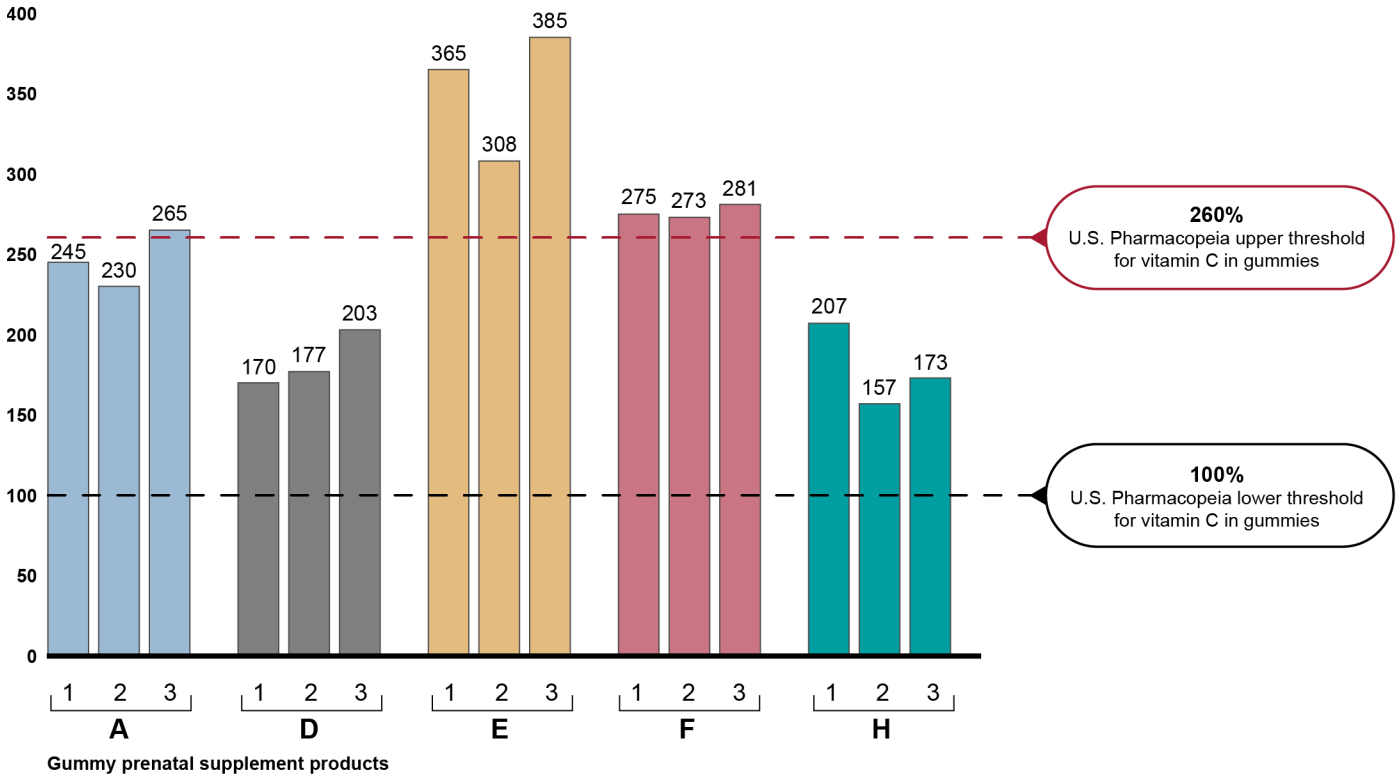


Source: GAO. | GAO-24-107042

Note: Vitamin A can be present in prenatal supplements in two forms: pre-formed vitamin A (e.g., retinol or retinyl palmitate) and pro-vitamin A carotenoids (e.g., beta-carotene). While only pre-formed vitamin A is associated with toxic effects at high doses, carotenoids alone are insufficient to maintain normal levels of vitamin A. Products I, J, and K are 100 percent provitamin A (beta-carotene).

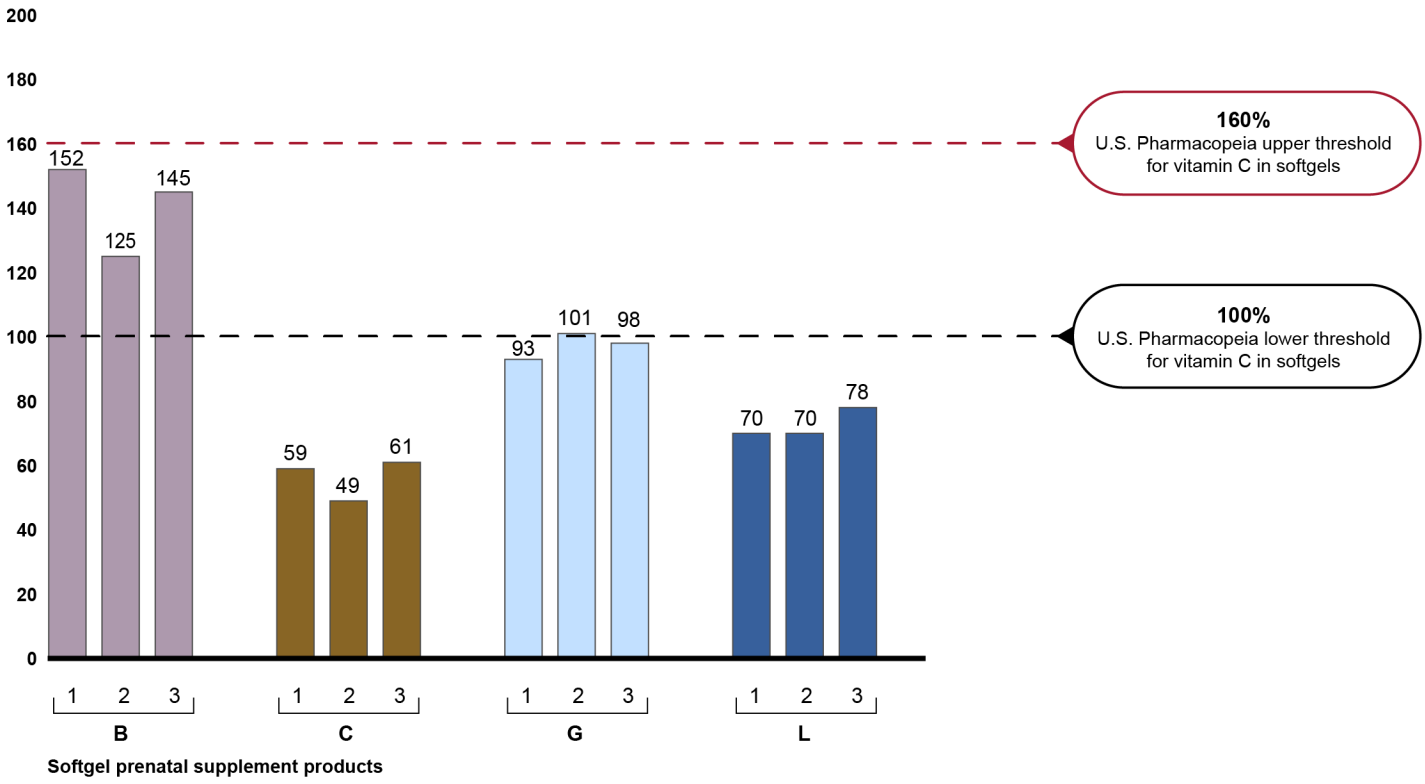
Vitamin C

Figure 12: Measured Amount of Vitamin C as a Percentage of the Label Amount for Three Lots of Each Gummy Prenatal Supplement Tested



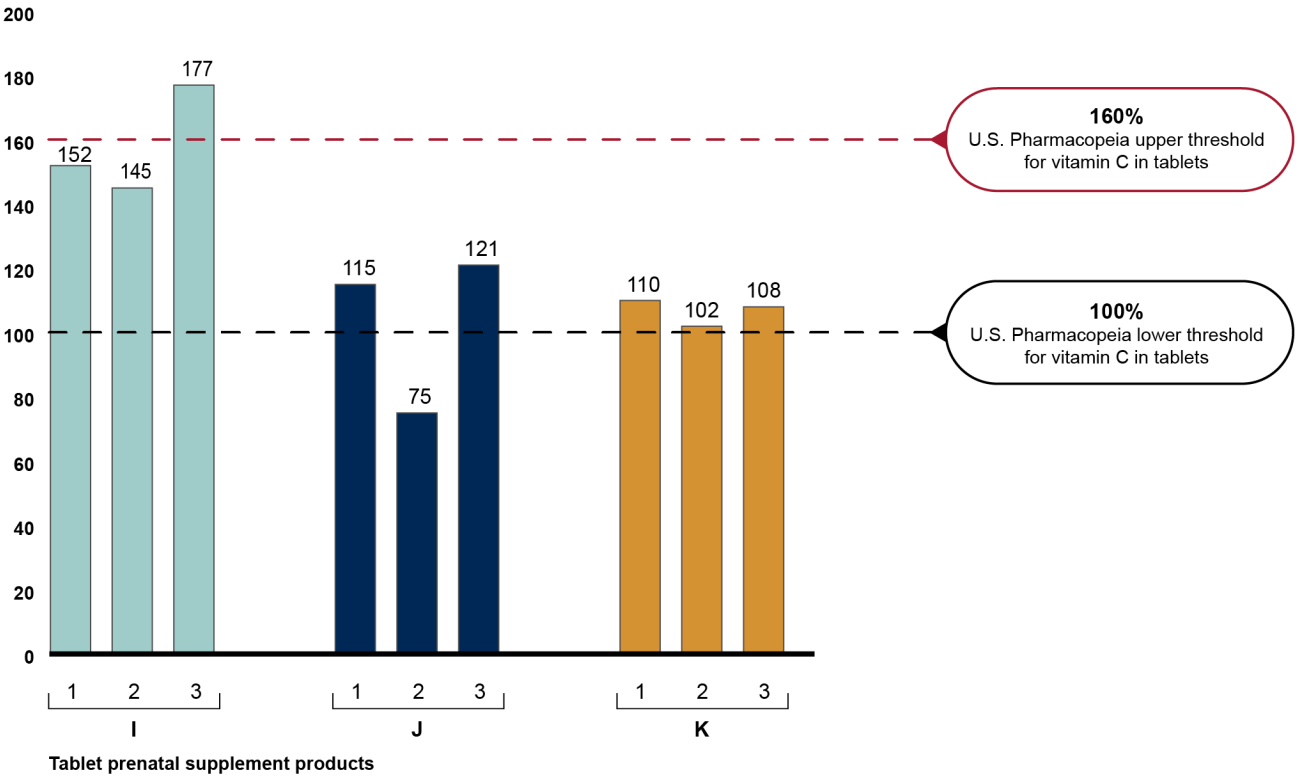
Source: GAO. | GAO-24-107042

Figure 13: Measured Amount of Vitamin C as a Percentage of the Label Amount for Three Lots of Each Softgel Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

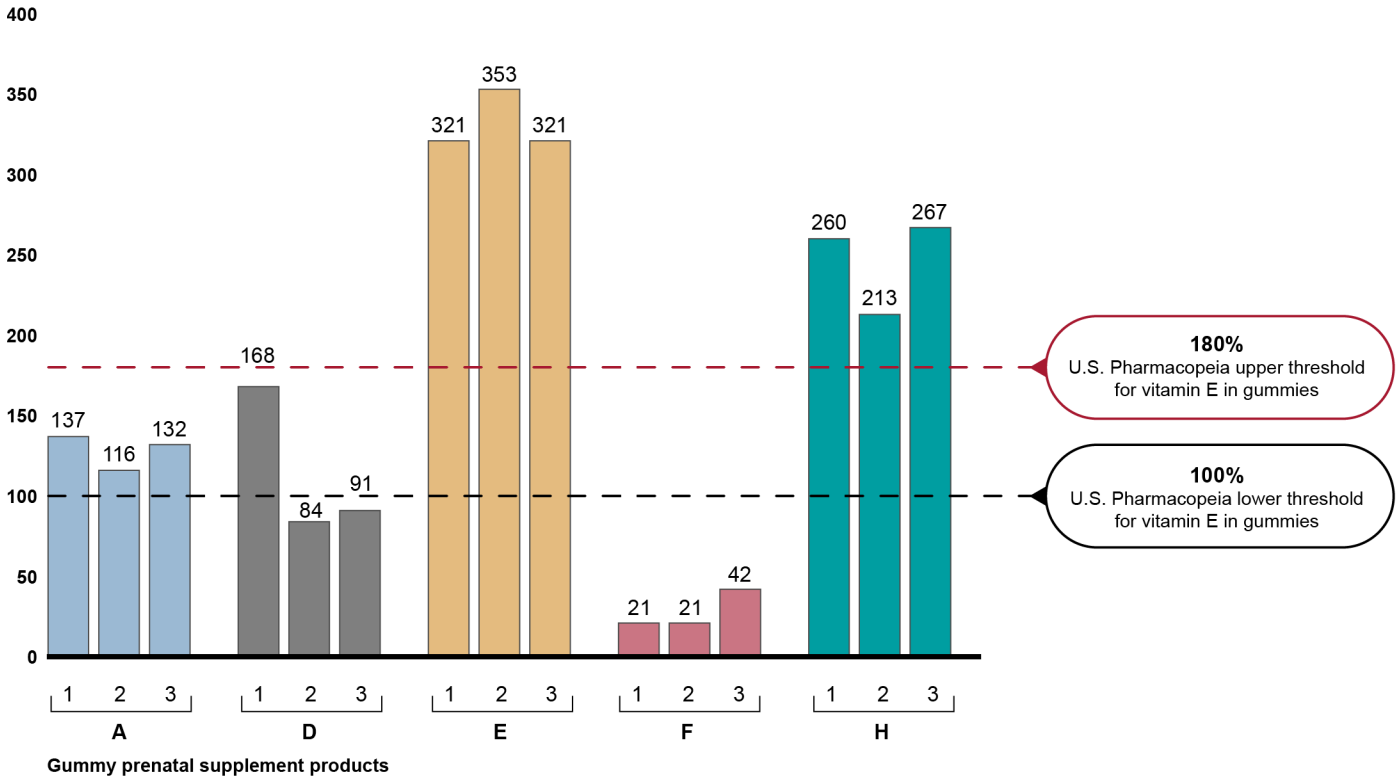
Figure 14: Measured Amounts of Vitamin C as a Percentage of the Label Amount for Three Lots of Each Tablet Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

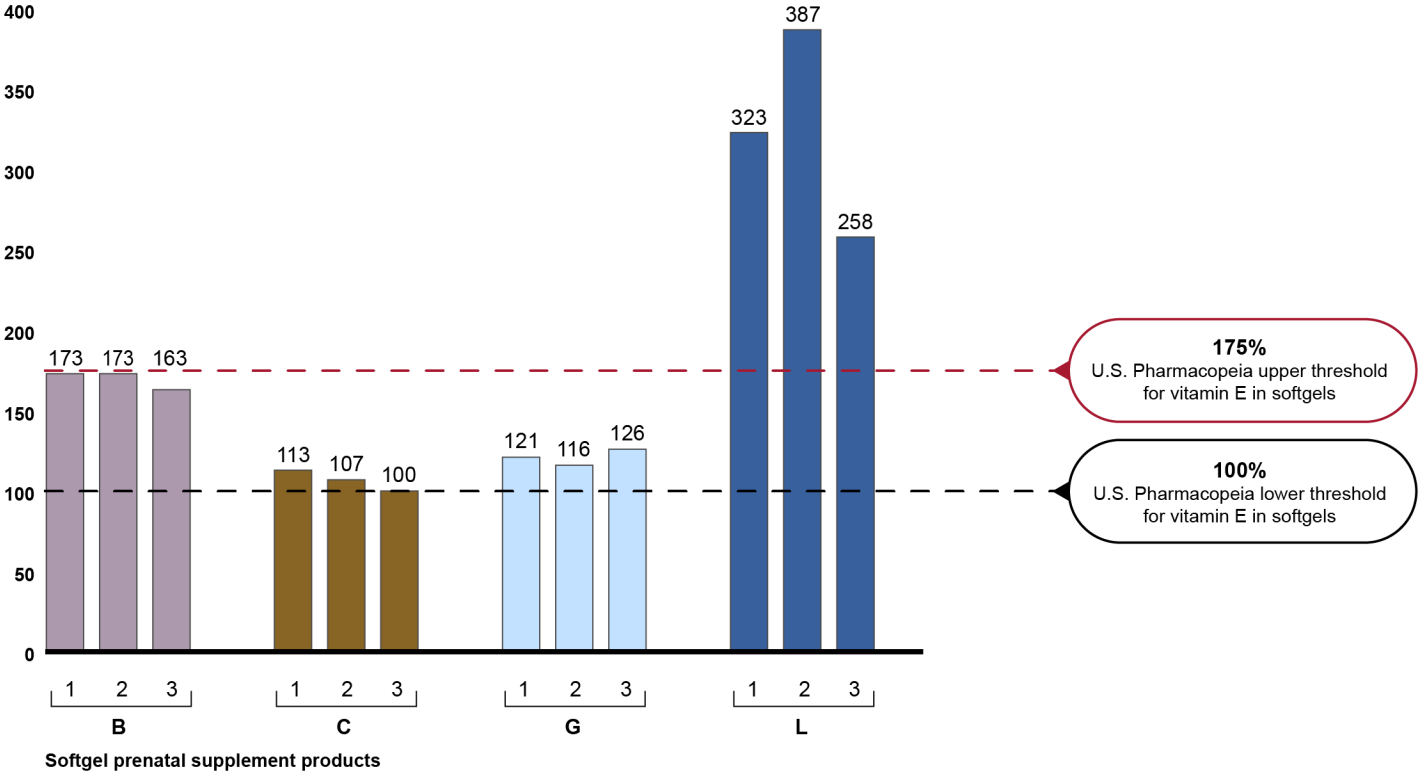
Vitamin E

Figure 15: Measured Amounts of Vitamin E as a Percentage of the Label Amount for Three Lots of Each Gummy Prenatal Supplement Tested



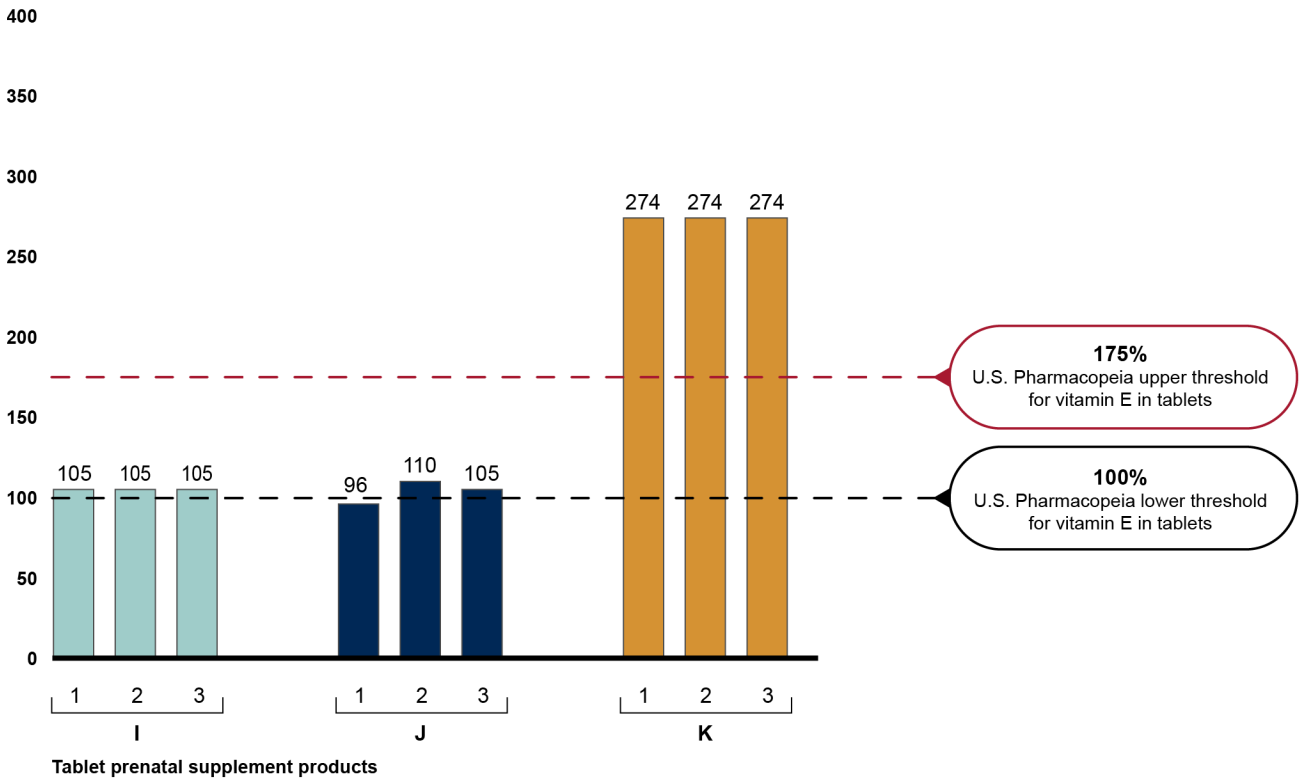
Source: GAO. | GAO-24-107042

Figure 16: Measured Amounts of Vitamin E as a Percentage of the Label Amount for Three Lots of Each Softgel Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

Figure 17: Measured Amounts of Vitamin E as a Percentage of the Label Amount for Three Lots of Each Tablet Prenatal Supplement Tested



Source: GAO. | GAO-24-107042

Tested Heavy Metals

We tested the 12 selected prenatal supplements for four heavy metal contaminants—arsenic, cadmium, lead, and mercury. As stated in our report (GAO-24-106689), arsenic and mercury were below the detection limit in all lots of all tested prenatal supplement products. None of the heavy metals were detected in any gummies we tested. Being below the detection limit does not necessarily mean that there is no amount of those metals present in the products. Rather, it means that any amount of those metals that may be present is extremely small and unlikely to be a health concern. Table 1 presents the results for cadmium and lead in each of the supplement products in which at least one of those metals was detected. All unprocessed data can be found in the CSV file available for download on the homepage of our report. The Food and Drug Administration (FDA) uses a daily exposure limit of 8.8 micrograms of lead per day for individuals of child-bearing age. FDA uses a daily exposure limit of 0.21–0.36 micrograms of cadmium per kilogram of body weight per day for any individual; this corresponds to a limit of 14.3–24.5 micrograms per day for a 150-pound individual.

Table 1: Measured Lead and Cadmium Values for Each Prenatal Supplement Product Tested[a]

Prenatal Supplement Product and Lot	Form (gummy, softgel, or tablet)	Cadmium (micrograms per daily serving)	Lead (micrograms per daily serving)
B1	Softgel	Not detected	0.15
B2	Softgel	Not detected	0.16
B3	Softgel	Not detected	0.15
C1	Softgel	0.53	0.10
C2	Softgel	Not detected	Not detected
C3	Softgel	0.50	Not detected
I1	Tablet	Not detected	0.28
I2	Tablet	Not detected	0.33
I3	Tablet	Not detected	0.33
J1	Tablet	Not detected	0.24
J2	Tablet	Not detected	0.22
J3	Tablet	Not detected	0.35
K1	Tablet	0.31	0.32
K2	Tablet	0.35	0.29
K3	Tablet	0.31	0.23
L1	Softgel	Not detected	0.21
L2	Softgel	Not detected	0.16
L3	Softgel	Not detected	0.18

Source: GAO. I GAO-24-107042

[a]Supplement products not listed did not have a detectable amount of cadmium or lead.