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 Accessible Version

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.

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Contents

Tested Nutrients	4
Folic Acid	5
lodine	8
Iron	11
Vitamin A	13
Vitamin C	16
Vitamin E	
Tested Heavy Metals	22

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. 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.

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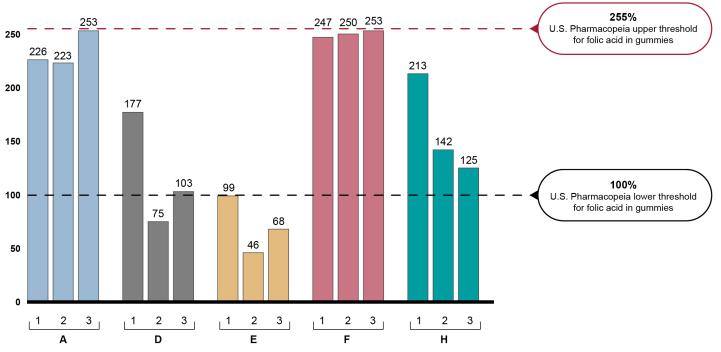
¹The Food and Drug Administration (FDA) considers class I nutrients below 100 percent of label amounts to be misbranded, according to FDA officials. In our analysis, we assumed that all tested nutrients in all tested supplements are class I nutrients (added nutrients in fortified or fabricated foods) 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

Percent of the label amount

300



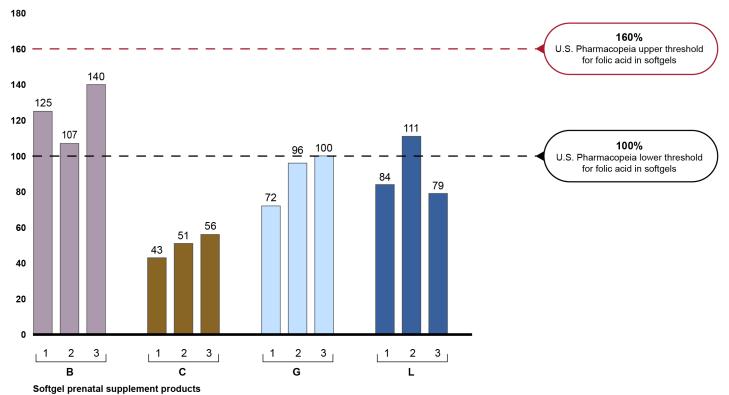
Gummy prenatal supplement products

Source: GAO. | GAO-24-107042

Gummy prenatal supplement products	Folic Acid (mcg) amounts per serving	
A1 % of label	226%	
A2 % of label	223%	
A3 % of label	253%	
D1 % of label	177%	
D2 % of label	75%	
D3 % of label	103%	
E1 % of label	99%	
E2 % of label	46%	
E3 % of label	68%	
F1 % of label	247%	
F2 % of label	250%	
F3 % of label	253%	
H1 % of label	213%	
H2 % of label	142%	
H3 % of label	125%	

U.S. Pharmacopeia lower threshold for folic acid in gummies: 100% U.S. Pharmacopeia upper threshold for folic acid in gummies: 255%

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

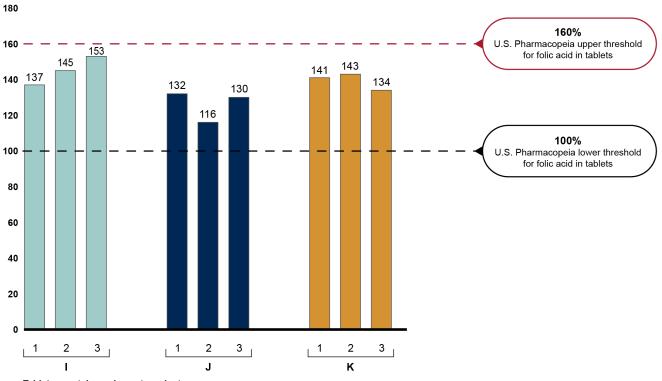


Source: GAO. | GAO-24-107042

Softgel prenatal supplement products	Folic Acid (mcg) amounts per serving	
B1 % of label	125%	
B2 % of label	107%	
B3 % of label	140%	
C1 % of label	43%	
C2 % of label	51%	
C3 % of label	56%	
G1 % of label	72%	
G2 % of label	96%	
G3 % of label	100%	
L1 % of label	84%	
L2 % of label	111%	
L3 % of label	79%	

U.S. Pharmacopeia lower threshold for folic acid in softgels: 100% U.S. Pharmacopiea upper threshold for folic acid in softgels: 160%

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



Tablet prenatal supplement products

Source: GAO. | GAO-24-107042

Tablet prenatal supplement products	Folic Acid (mcg) amounts per serving	
I1 % of label	137%	
I2 % of label	145%	
I3 % of label	153%	
J1 % of label	132%	
J2 % of label	116%	
J3 % of label	130%	
K1 % of label	141%	
K2 % of label	143%	
K3 % of label	134%	

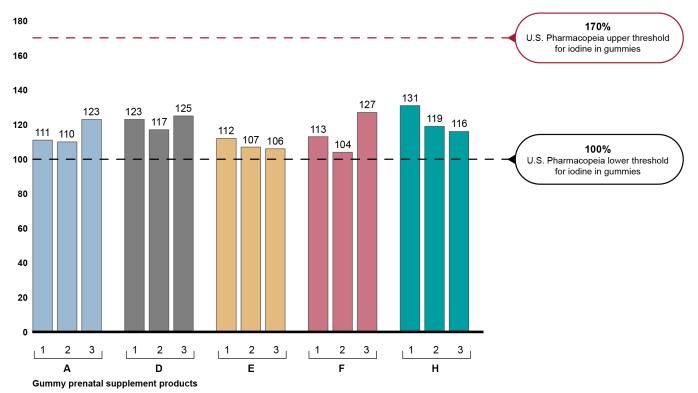
U.S. Pharmacopeia lower threshold for folic acid in tablets: 100%

U.S. Pharmacopeia upper threshold for folic acid in tablets: 160%

lodine

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

Percent of the label amount

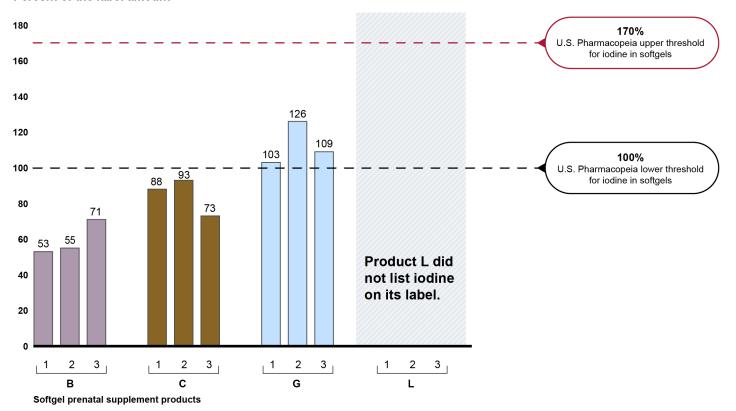


Source: GAO. | GAO-24-107042

Gummy prenatal supplement products	lodine (mcg) amounts per serving	
A1 % of label	111%	
A2 % of label	110%	
A3 % of label	123%	
D1 % of label	123%	
D2 % of label	117%	
D3 % of label	125%	
E1 % of label	112%	
E2 % of label	107%	
E3 % of label	106%	
F1 % of label	113%	
F2 % of label	104%	
F3 % of label	127%	
H1 % of label	131%	
H2 % of label	119%	
H3 % of label	116%	
H1 % of label	131%	

U.S. Pharmacopeia lower threshold for iodine in gummies: 100% U.S. Pharmacopeia upper threshold for iodine in gummies: 170%

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

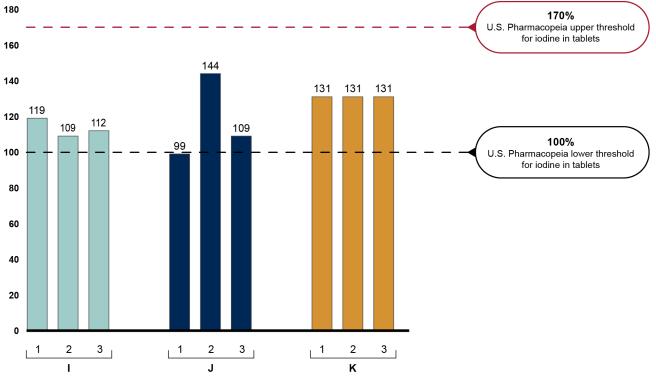


Source: GAO. | GAO-24-107042

Softgel prenatal supplement products	lodine (mcg) amounts per serving	
B1 % of label	53%	
B2 % of label	55%	
B3 % of label	71%	
C1 % of label	88%	
C2 % of label	93%	
C3 % of label	73%	
G1 % of label	103%	
G2 % of label	126%	
G3 % of label	109%	
L1 % of label	Product L did not list iodine on its label.	
L2 % of label		
L3 % of label		

U.S. Pharmacopeia lower threshold for iodine in softgels: 100% U.S. Pharmacopeia upper threshold for iodine in softgels: 170%

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



Tablet prenatal supplement products

Source: GAO. | GAO-24-107042

Tablet prenatal supplement products	lodine (mcg) amounts per serving	
I1 % of label	119%	
I2 % of label	109%	
I3 % of label	112%	
J1 % of label	99%	
J2 % of label	144%	
J3 % of label	109%	
K1 % of label	131%	
K2 % of label	131%	
K3 % of label	131%	

U.S. Pharmacopeia lower threshold for iodine in tablets: 100%

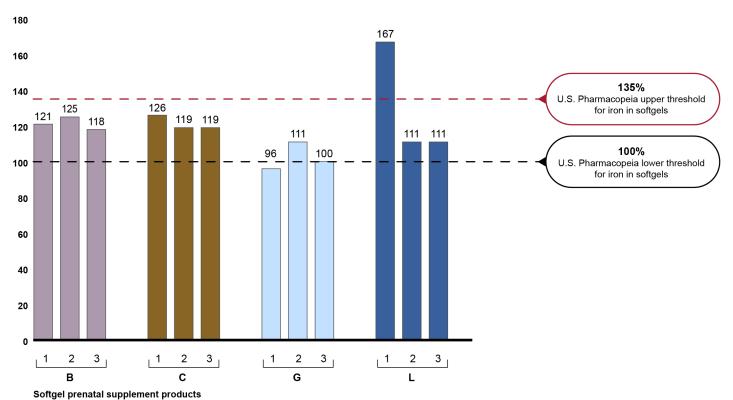
U.S. Pharmacopeia upper threshold for iodine in tablets: 170%

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

Percent of the label amount

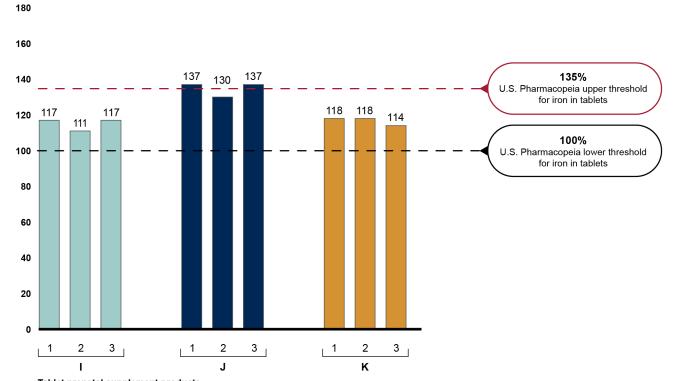


Source: GAO. | GAO-24-107042

Softgel prenatal supplement products	Iron (mg) amounts per serving	
B1 % of label	121%	
B2 % of label	125%	
B3 % of label	118%	
C1 % of label	126%	
C2 % of label	119%	
C3 % of label	119%	
G1 % of label	96%	
G2 % of label	111%	
G3 % of label	100%	
L1 % of label	167%	
L2 % of label	111%	
L3 % of label	111%	

U.S. Pharmacopeia lower threshold for iron in softgels: 100% U.S. Pharmacopeia upper threshold for iron in softgels: 135%

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



Tablet prenatal supplement products

Source: GAO. | GAO-24-107042

Tablet prenatal supplement products	Iron (mg) amounts per serving	
I1 % of label	117%	
I2 % of label	111%	
I3 % of label	117%	
J1 % of label	137%	
J2 % of label	130%	
J3 % of label	137%	
K1 % of label	118%	
K2 % of label	118%	
K3 % of label	114%	

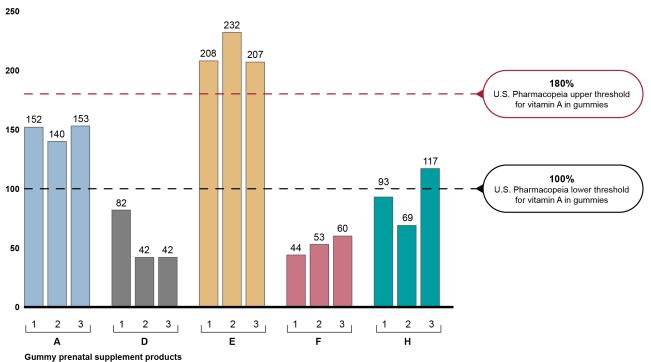
U.S. Pharmacopeia lower threshold for iron in tablets: 100%

U.S. Pharmacopeia upper threshold for iron in tablets: 135%

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**

Percent of the label amount



Source: GAO. | GAO-24-107042

Gummy prenatal supplement products	Vitamin A (mcg RAE) amounts per serving
A1 % of label	152%
A2 % of label	140%
A3 % of label	153%
D1 % of label	82%
D2 % of label	42%
D3 % of label	42%
E1 % of label	208%
E2 % of label	232%
E3 % of label	207%
F1 % of label	44%
F2 % of label	53%
F3 % of label	60%
H1 % of label	93%
H2 % of label	69%
H3 % of label	117%

U.S. Pharmacopeia lower threshold for vitamin A in gummies: 100% U.S. Pharmacopeia upper threshold for vitamin A in gummies: 180%

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).

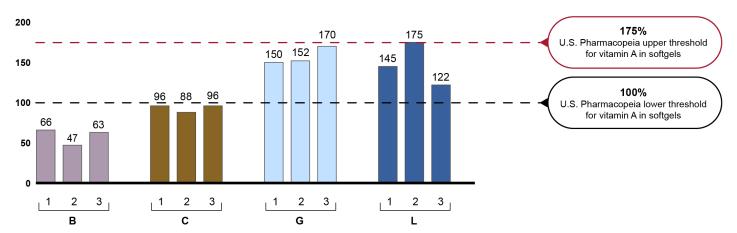
Figure 10: Measured Amount of Vitamin A as a Percentage of the Label Amount for Three Lots of Each Softgel Prenatal Supplement Tested



350

300

250



Softgel prenatal supplement products

Source: GAO. | GAO-24-107042

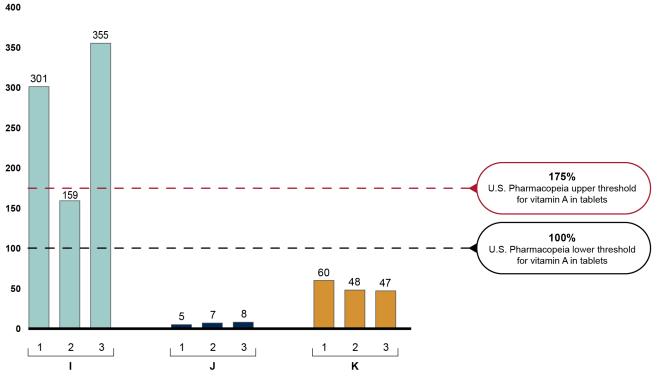
Softgel prenatal supplement products	Vitamin A (mcg RAE) amounts per serving
B1 % of label	66%
B2 % of label	47%
B3 % of label	63%
C1 % of label	96%
C2 % of label	88%
C3 % of label	96%
G1 % of label	150%
G2 % of label	152%
G3 % of label	170%
L1 % of label	145%
L2 % of label	175%
L3 % of label	122%

U.S. Pharmacopeia lower threshold for vitamin A in softgels: 100% U.S. Pharmacopeia upper threshold for vitamin A in softgels: 175%

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). Product 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



Tablet prenatal supplement products

Source: GAO. | GAO-24-107042

Tablet prenatal supplement products	Vitamin A (mcg RAE) amounts per serving
I1 % of label	301%
I2 % of label	159%
I3 % of label	355%
J1 % of label	5%
J2 % of label	7%
J3 % of label	8%
K1 % of label	60%
K2 % of label	48%
K3 % of label	47%

U.S. Pharmacopeia lower threshold for vitamin A in tablets: 100%

U.S. Pharmacopeia upper threshold for vitamin A in tablets: 175%

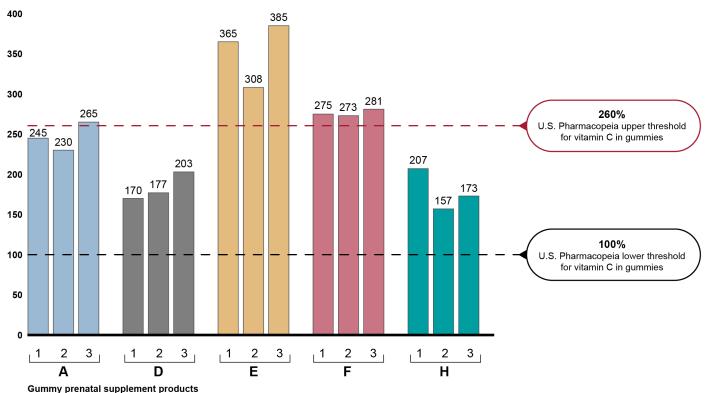
Source: GAO. | GAO-24-107042

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

Percent of the label amount



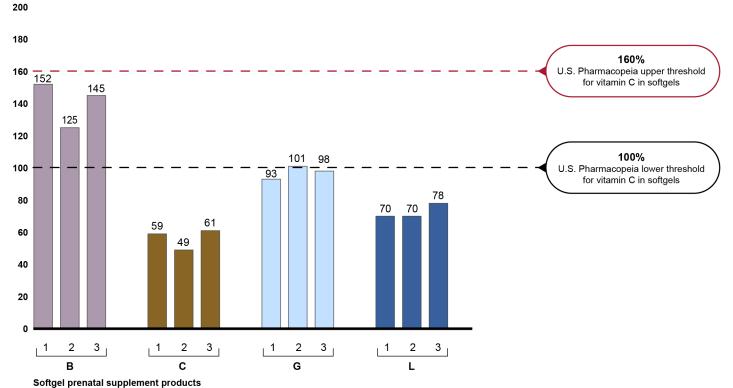
Guilling prenatal supplement produc

Source: GAO. | GAO-24-107042

Gummy prenatal supplement products	Vitamin C (mg) amounts per serving	
A1 % of label	245%	
A2 % of label	230%	
A3 % of label	265%	
D1 % of label	170%	
D2 % of label	177%	
D3 % of label	203%	
E1 % of label	365%	
E2 % of label	308%	
E3 % of label	385%	
F1 % of label	275%	
F2 % of label	273%	
F3 % of label	281%	
H1 % of label	207%	
H2 % of label	157%	
H3 % of label	173%	

U.S. Pharmacopeia lower threshold for vitamin C in gummies: 100% U.S. Pharmacopeia upper threshold for vitamin C in gummies: 260%

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

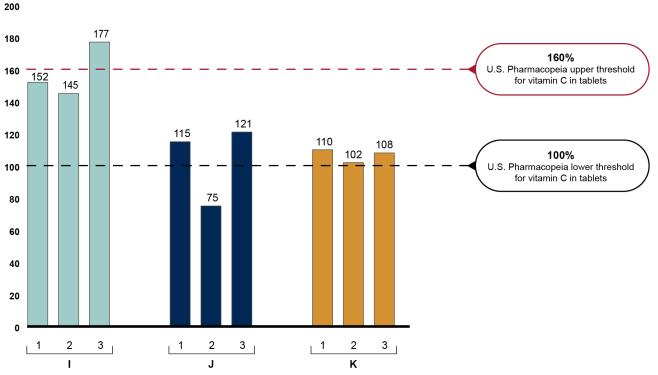


Source: GAO. | GAO-24-107042

Softgel prenatal supplement products Vitamin C (mg) amounts per serving B1 % of label 152% 125% B2 % of label B3 % of label 145% C1 % of label 59% C2 % of label 49% C3 % of label 61% G1 % of label 93% G2 % of label 101% G3 % of label 98% L1 % of label 70% L2 % of label 70% L3 % of label 78%

U.S. Pharmacopeia lower threshold for vitamin C in softgels: 100% U.S. Pharmacopeia upper threshold for vitamin C in softgels: 160%

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



Tablet prenatal supplement products

Source: GAO. | GAO-24-107042

Tablet prenatal supplement products	Vitamin C (mg) amounts per serving	
I1 % of label	152%	
I2 % of label	145%	
I3 % of label	177%	
J1 % of label	115%	
J2 % of label	75%	
J3 % of label	121%	
K1 % of label	110%	
K2 % of label	102%	
K3 % of label	108%	

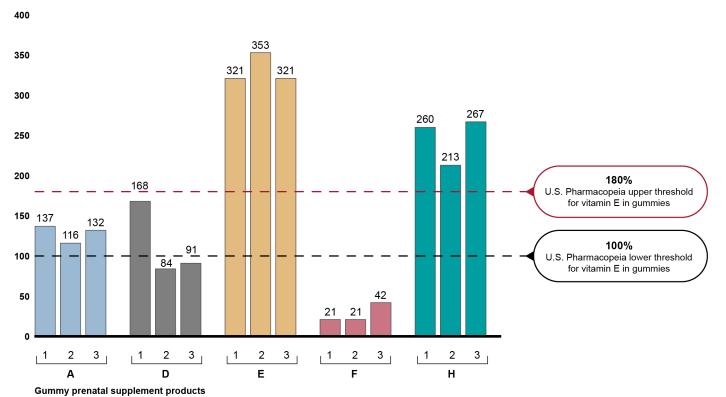
U.S. Pharmacopeia lower threshold for vitamin C in tablets: 100%

U.S. Pharmacopeia upper threshold for vitamin C in tablets: 160%

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

Percent of the label amount

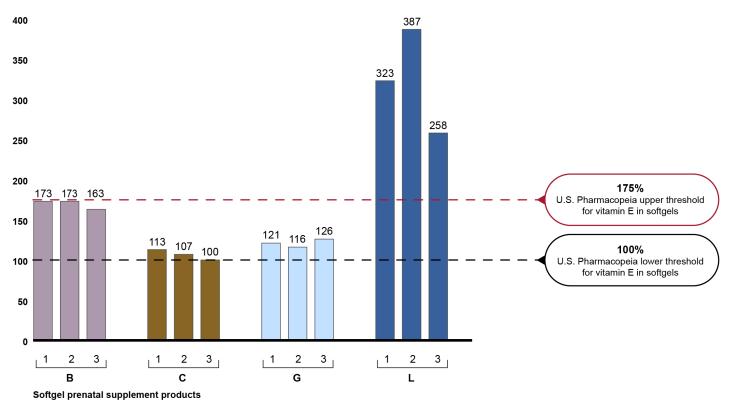


Source: GAO. | GAO-24-107042

Gummy prenatal supplement products	Vitamin E (mg) amounts per serving	
A1 % of label	137%	
A2 % of label	116%	
A3 % of label	132%	
D1 % of label	168%	
D2 % of label	84%	
D3 % of label	91%	
E1 % of label	321%	
E2 % of label	353%	
E3 % of label	321%	
F1 % of label	21%	
F2 % of label	21%	
F3 % of label	42%	
H1 % of label	260%	
H2 % of label	213%	
H3 % of label	267%	

U.S. Pharmacopeia lower threshold for vitamin E in gummies: 100% U.S. Pharmacopeia upper threshold for vitamin E in gummies: 180% 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

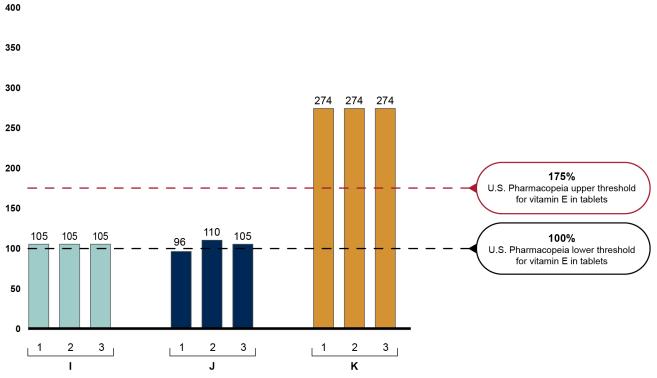


Source: GAO. | GAO-24-107042

Softgel prenatal supplement products	Vitamin E (mg) amounts per serving	
B1 % of label	173%	
B2 % of label	173%	
B3 % of label	163%	
C1 % of label	113%	
C2 % of label	107%	
C3 % of label	100%	
G1 % of label	121%	
G2 % of label	116%	
G3 % of label	126%	
L1 % of label	323%	
L2 % of label	387%	
L3 % of label	258%	

U.S. Pharmacopeia lower threshold for vitamin E in softgels: 100% U.S. Pharmacopeia upper threshold for vitamin E in softgels: 175%

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



Tablet prenatal supplement products

Source: GAO. | GAO-24-107042

Tablet prenatal supplement products	Vitamin E (mg) amounts per serving	
I1 % of label	105%	
I2 % of label	105%	
I3 % of label	105%	
J1 % of label	96%	
J2 % of label	110%	
J3 % of label	105%	
K1 % of label	274%	
K2 % of label	274%	
K3 % of label	274%	

U.S. Pharmacopeia lower threshold for vitamin E in tablets: 100%

U.S. Pharmacopeia upper threshold for vitamin E in tablets: 175%

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.

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
l1	Tablet	Not detected	0.28
12	Tablet	Not detected	0.33
13	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

^aSupplement products not listed did not have a detectable amount of cadmium or lead.