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Counsel for Plaintiff and the Proposed Classes

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

THAMAR SANTISTEBAN CORTINA, on behalf of herself, all others similarly situated and the general public,

Plaintiff,

v.

WAL-MART, INC.,

Defendant.

Case No: '13CV2054 JAH DHB

CLASS ACTION

COMPLAINT FOR:

VIOLATIONS OF THE MAGNUSON-MOSS WARRANTY ACT;

VIOLATIONS OF ARKANSAS AND CALIFORNIA CONSUMER PROTECTION STATUTES; AND

BREACHES OF EXPRESS AND IMPLIED WARRANTIES

DEMAND FOR JURY TRIAL

THAMAR SANTISTEBAN CORTINA, on behalf of herself, all others similarly situated, and the general public, by and through her undersigned counsel, hereby sues Defendant WAL-MART STORES, INC., and alleges the following upon her own knowledge, or where she lacks personal knowledge, upon information and belief and the investigation of her counsel.

INTRODUCTION

1. Coenzyme Q10, or CoQ10, is a dietary supplement with many potential benefits, especially to heart health.

2. WAL-MART sells a self-branded CoQ10 product, Equate Co-Q10 ("Equate"), which claims it provides "clinical strength," "high absorption," and "3x better absorption" than competing products:

3. The claim is false. Independent laboratory analysis demonstrates Equate does not meet the industry standard dissolution for effectiveness, much less offer "3 times better absorption" than competitors.

4. Plaintiff brings this class action to remedy the damage caused to consumers by WAL-MART's defective product and false advertising.

JURISDICTION & VENUE

5. The Court has original jurisdiction pursuant to 28 U.S.C. § 1331 because this action raises a federal question under the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301 *et seq.* The Court also has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), the Class Action Fairness Act, because the matter in controversy exceeds the sum or value of $5,000,000 exclusive of interest and costs and because more than two-thirds of the members of the classes reside in states other than the states in which Defendants are citizens.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Plaintiff resides in and suffered injuries as a result of Defendant's acts in this District, many of the acts and transactions giving rise to this action occurred in this District, and Defendant is authorized to conduct business in this District, does substantial business in this District, has intentionally availed itself of the laws and markets of this District, and is subject to personal jurisdiction in this District.

PARTIES

7. Plaintiff THAMAR SANTISTEBAN CORTINA is a resident of Bonita, California, in San Diego County.

8. Defendant WAL-MART STORES, INC. is a Delaware corporation with its principal place of business at 702 Southwest 8th Street, Bentonville, Arkansas 72716.

FACTS

I. COENZYME Q10

9. CoQ10, also known as ubiquinone (its active form is known as ubiquinol), is a naturally occurring anti-oxidant compound for energy production within cells, manufactured in the heart, liver, kidneys and pancreas. CoQ10 is often taken to help to treat or prevent congestive heart failure and has been used with anecdotal and varying success in treating or mitigating a variety of other conditions.

10. The body normally produces sufficient CoQ10, but it can be depleted by aging, heart disease, and some medications, especially statins. While small amounts of CoQ10 are available in meat, dietary supplementation is the most common way to increase the body's CoQ10 levels. CoQ10 is the fourth most popular supplement in the U.S., with sales of $519 million in 2011.

II. WAL-MART EQUATE CO Q-10

11. Wal-Mart sells Equate in its retail stores throughout the United States, for $9.97 per bottle.

12. Equate's packaging makes the following representations:

- "Clinical Strength"
- "High Absorption"
- "3 times better absorption"
- "Helps support Heart Health"
- "Supports heart and vascular health"
- "Promotes health blood pressure levels"
- "Essential for energy production"
- "Beneficial to Statin Drug Users"
- "Powerful natural antioxidants"
- "Compare to Qunol™ Ultra CoQ-10"

13. A true and correct reproduction of Equate High Absorption Co Q-10's packaging and label, replicated in less detail above, is attached hereto as Exhibit 1.

III. PLAINTIFF'S EQUATE PURCHASES

14. Plaintiff has used CoQ10 supplements since 2008.

15. On several occasions, plaintiff purchased Equate at the Wal-Mart located at 1360 Eastlake Parkway, Chula Vista, California, 91915 or at the Wal-Mart located at 1200 Highland Avenue, National City, California 91950.

16. Plaintiff's most recent Equate purchase was in mid-July, 2013.

17. For each Equate purchase, plaintiff relied on Wal-Mart's representation that Ultra provides "clinical strength," "high absorption," and "3 times better absorption" than competing products, that it was comparable to more expensive products like Qunol Ultra CoQ-10, and that it generally supported heart health.

IV. USP

18. The U.S. Pharmacopeial Convention, or USP, is a nonprofit scientific organization whose participants, working under strict conflict-of-interest rules, set standards for dietary supplements that are enforceable by the Food and Drug Administration.

19. These USP standards are published in the joint compendia of the USP and the National Formulary, known as USP-NF. The Dietary Supplemental Health and Education Act of 1994 amendments to the Federal Food, Drug, and Cosmetic Act name USP-NF as official compendia for dietary supplements.

20. USP-NF consists of Monographs, General Chapters, and General Notices.

21. Monographs include the name of an ingredient or preparation; its definition; its packaging, storage, and labeling requirements; and its specification, which consists of a series of tests, procedures for the tests, and acceptance criteria that require use of the official USP Reference Standards.

22. General Chapters set forth tests and procedures referred to in multiple monographs.

23. General Notices provide definitions for terms used in monographs, as well as information necessary to interpret monograph requirements.

24. A true and correct copy of the USP monograph for Ubidecarenone[1] Capsules ("CoQ10 Monograph"), USP35 at 1461-62, is attached hereto as Exhibit 2, and expressly incorporated into this Complaint.

25. The CoQ10 Monograph provides that ubidecarenone capsules, like the Equate CoQ10 soft gels, must "contain NLT [No Less Than] 90% and NMT [No More Than] 115% of the labeled amount of" CoQ10.

26. The CoQ10 Monograph further provides that ubidecarenone capsules, like the Equate CoQ10 soft gels, must meet performance tests described in the General Chapter on Disintegration and Dissolution, i.e., USP-NF General Chapter <2040>.

27. A true and correct copy of USP-NF <2040> is attached hereto as Exhibit 3, and expressly incorporated into this Complaint.

28. The CoQ10 Monograph further provides that ubidecarenone capsules "labeled to contain a water-soluble form of ubidecarenone," like Equate CoQ10, must "meet the requirements for the test for *Dissolution*," including "**Tolerances:** NLT 75% of the labeled amount of ubidecarenone . . . is dissolved."

29. Dietary supplement manufacturers may voluntarily submit their products to USP for verification. USP performs laboratory analysis then, following its standards, determines whether the supplement is of sufficient quality, purity, strength, and appropriately disintegrates and releases its contents into the body within a specified period of time. If verified, the product may then bear a "USP Verified" seal.

30. WAL-MART has not submitted Equate for USP verification.

[1] Another, more formal name for CoQ10.

31. Equate is labeled to contain 100mg of CoQ10. Accordingly, pursuant to the CoQ10 Monograph, Equate must contain at least 90mg of CoQ10, and must exhibit at least 75% dissolution.

V. INDEPENDENT LABORATORY TESTING SHOWS EQUATE DOES NOT MEET THE USP DEFINITION OF "UBIDECARENONE CAPSULE" BECAUSE IT CONTAINS LESS THAN 90% OF ITS ADVERTISED COQ10

32. Between August 2, 2013 and August 12, 2013, Covance, an independent laboratory that provides food and dietary supplement testing, analyzed samples from two different lots of Equate.

33. A true and correct copy of Covance's Certificate of Analysis with respect to the results from its analysis of Equate Lot 1, with attorney work product redacted, is attached hereto as Exhibit 4.

34. A true and correct copy of Covance's Certificate of Analysis with respect to the results from its analysis of Equate Lot 2, with attorney work product redacted, is attached hereto as Exhibit 5.

35. Applying the applicable testing standards, Covance determined that Equate does not provide 90mg of CoQ10, but instead:

a. For Lot 1, an average, across 6 samples, of only 55.32 mg; and

b. For Lot 2, an average, across 6 samples, of only 55.53 mg.

VI. INDEPENDENT LABORATORY REPORTS SHOW EQUATE DOES NOT ADEQUATELY DISSOLVE IN THE STOMACH

36. Applying the applicable USP specifications and procedures, Covance also determined that Equate fails the specification's dissolution test, not providing 75% dissolution as required, but instead:

a. For Lot 1, an average, across 6 samples, of only 41.18% dissolution; and

b. For Lot 2, an average, across 6 samples, of only 41.3% dissolution.

37. What this means practically is that Equate fails to provide consumers the full benefit of the product advertised. Equate's 41.3% dissolution level is just 55% the 75% dissolution level required.

38. Moreover, for Equate to provide "3 times better absorption" than competing products, those competing products must provide just 13.8% absorption (41.3% ÷ 3).

WAL-MART'S UNLAWFUL ACTS & PRACTICES

I. FALSE OR MISLEADING ADVERTISING

A. WAL-MART's Affirmative Misrepresentations

39. WAL-MART's claim that Equate provides "clinical strength," "high absorption," and "3 times better absorption" than competitors is false and misleading because the product does not provide sufficient CoQ10, nor dissolve sufficiently to provide adequate absorption, much less "3 times" that of its competitors.

40. WAL-MART's claim that it generally supports heart health and is beneficial to statin users, while perhaps literally true, is also misleading inasmuch as the product supports heart health to a lesser degree, and provides less benefit to statin users, than advertised, or than consumers would reasonably expect.

41. WAL-MART's claim that Equate is comparable to Qunol Ultra CoQ-10 is also false and misleading because there is no evidence that the products are equivalent in ingredients, quality, or dissolution.

B. WAL-MART's Omissions of Material Facts

42. In labeling Equate, WAL-MART deceptively omitted information that would have been material to consumers' purchasing decisions, e.g., that Equate does not adequately dissolve.

43. In addition, Equate's packaging does not provide any citation for its "3 times" claim, providing consumers with no means of determining the claim's legitimacy, for

example by reference to a study or other information on which WAL-MART bases the "3 times" claim.

RELIANCE AND INJURY

44. For each purchase of Equate, plaintiff relied on WAL-MART's representation that the product provides "clinical strength," "high absorption," and "3 times better absorption" than competing CoQ10 supplements. In addition, plaintiff relied on WAL-MART's representations that Equate generally supports heart health.

45. Plaintiff would not have purchased Equate absent WAL-MART's false and misleading representation about its "clinical strength," "high absorption," and "3 times better absorption."

46. But Equate does not provide three times better absorption than fair marketplace comparators. Because Equate is actually only partially effective, plaintiff did not receive what she paid for, and lost money in amount of her Equate purchases.

47. Plaintiff purchased Equate instead of competing products based on the false statements and misrepresentations described herein.

48. Equate was unsatisfactory to plaintiff because it did not provide the full benefit advertised.

49. Plaintiff would not have paid the price she did for Equate, and may not have been willing to purchase Equate at all, if she knew that it provides substantially less CoQ10, and substantially less dissolution, than the USP CoQ10 Monograph requires. Plaintiff paid a price premium due to WAL-MART's fraudulent conduct.

CLASS ACTION ALLEGATIONS

50. Pursuant to Rule 23, plaintiff seeks to represent a Nationwide Class comprised of all persons in the United States who purchased WAL-MART Equate primarily for personal, family, or household use, and not for resale.

51. Pursuant to Rule 23, plaintiff also seeks to represent a California Subclass comprised of all persons in California who purchased WAL-MART Equate primarily for personal, family, or household use, and not for resale.

52. The members in the proposed class and subclass are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all class members in a single action will provide substantial benefits to the parties and Court.

53. Questions of law and fact common to plaintiff and the class include:

A. Whether Equate is a consumer product, whether the class members are consumers, and whether WAL-MART is a supplier and warrantor, within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301;

B. Whether through Equate's labeling claims, WAL-MART made express or implied warranties to purchasers;

C. Whether WAL-MART breached express warranties by failing to provide Equate in conformance with promises or descriptions that became a basis for the bargain;

D. Whether WAL-MART breached implied warranties by failing to provide merchantable goods in selling Equate to the class members, or by selling Equate that was not fit for its particular purpose of supplementing the body's natural CoQ10 production sufficiently to support heart health and benefit statin users;

E. Whether WAL-MART's sale of Equate constitutes the sale of "goods," or "business, commerce, or trade," within the meaning of Ark. Code Ann. §§ 4-88-102(3), 4-88-107;

F. Whether Equate has actually malfunctioned or a defect manifested itself;

G. Whether WAL-MART knowingly made false representations about Equate's characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification, or that Equate is of a particular standard, quality, grade, style, or model, within the meaning of Ark. Code Ann. §§ 4-88-107(a)(1);

H. Whether WAL-MART advertised Equate with the intent not to sell Equate as advertised, within the meaning of Ark. Code Ann. §§ 4-88-107(a)(3);

I. Whether any of WAL-MART's practices are unconscionable within the meaning of Ark. Code Ann. §§ 4-88-107(a)(10), i.e., whether any practice affronts the sense of justice, decency, or reasonableness;

J. Whether any of WAL-MART's practices are false or deceptive within the meaning of Ark. Code Ann. §§ 4-88-107(a)(10);

K. Whether any of WAL-MART's deceptive consumer-oriented acts or practices were misleading in a material respect;

L. Whether any of WAL-MART's practices violate public policy found in Arkansas' statutes or constitution;

M. Whether WAL-MART made statements concerning Equate's absorption and effectiveness that were likely to deceive the public;

N. Whether WAL-MART made any statement it knew or should have known was false or misleading;

O. Whether any of WAL-MART's practices were immoral, unethical, unscrupulous, or substantially injurious to consumers;

P. Whether the utility of any of WAL-MART's practices, if any, outweighed the gravity of the harm to its victims;

Q. Whether WAL-MART's conduct violated public policy as declared by specific constitutional, statutory or regulatory provisions;

R. Whether the consumer injury caused by WAL-MART's conduct was substantial, not outweighed by benefits to consumers or competition, and not one consumers themselves could reasonably have avoided;

S. Whether WAL-MART's conduct or any of its acts or practices violated the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2103

et seq., the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. §§ 4-88-101, *et seq.*, the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*, the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*, or any other law;

T. Whether WAL-MART's policies, acts, and practices with respect to Equate were designed to, and did result in the purchase and use of Equate by the class members primarily for personal, family, or household purposes;

U. Whether WAL-MART misrepresented the source, sponsorship, approval, or certification of Equate within the meaning of Cal. Civ. Code § 1770(a)(2);

V. Whether WAL-MART misrepresented Equate's affiliation, connection, or association with, or certification by, another, within the meaning of Cal. Civ. Code § 1770(a)(3);

W. Whether WAL-MART represented that Equate has characteristics, uses, or benefits which it does not have, within the meaning of Cal. Civ. Code § 1770(a)(5);

X. Whether WAL-MART represented that Equate is original or new if it has deteriorated unreasonably or is altered, within the meaning of Cal. Civ. Code § 1770(a)(6);

Y. Whether WAL-MART represented Equate is of a particular standard, quality, or grade, when it was really of another, within the meaning of Cal. Civ. Code § 1770(a)(7);

Z. Whether WAL-MART disparaged the goods, services, or business of another by false or misleading representation of fact, within the meaning of Cal. Civ. Code § 1770(a)(8);

AA. Whether WAL-MART advertised Equate with the intent not to sell it as advertised, within the meaning of Cal. Civ. Code § 1770(a)(9);

BB. Whether WAL-MART represented that Equate has been supplied in accordance with a previous representation when it has not, within the meaning of Cal. Civ. Code § 1770(a)(16)

CC. The proper equitable and injunctive relief;

DD. The proper amount of actual or compensatory damages;

EE. The proper amount of restitution or disgorgement;

FF. The proper amount of punitive damages; and

GG. The proper amount of reasonable litigation expenses and attorneys' fees.

54. Plaintiff's claims are typical of class members' claims in that they are based on the same underlying facts, events, and circumstances relating to WAL-MART's conduct.

55. Plaintiff will fairly and adequate represent and protect the interests of the class, has no interests incompatible with the interests of the class, and has retained counsel competent and experienced in class action litigation.

56. The class is sufficiently numerous, as both the class and subclass contain at least thousands of members who purchased the WAL-MART Equate at issue in this action.

57. Class treatment is superior to other options for resolution of the controversy because the relief sought for each class member is small such that, absent representative litigation, it would be infeasible for class members to redress the wrongs done to them.

58. Questions of law and fact common to the class predominate over any questions affecting only individual class members.

59. As a result of the foregoing, class treatment is appropriate under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3).

FIRST CAUSE OF ACTION

VIOLATIONS OF THE MAGNUSON-MOSS WARRANTY ACT,

15 U.S.C. §§ 2301 *ET SEQ.*

(By the Nationwide Class)

60. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

61. Equate is a consumer product within the meaning of 15 U.S.C. § 2301(1).

62. Plaintiff and the class members are consumers within the meaning of 15 U.S.C. § 2301(3).

63. Defendant WAL-MART is a supplier and warrantor as defined in 15 U.S.C. §§ 2301(4) & (5).

64. The Magnuson-Moss Warranty Act permits a consumer to recover damages caused "by the failure of a supplier, warrantor, or service contractor to comply with any obligation under his [Act], or under a written warranty, implied warranty, or service contract." 15 U.S.C. § 2310(d)(1).

65. WAL-MART's claims that Equate provides "clinical strength," "high absorption," and "3 times better absorption" is a "written warranty" within the meaning of the Act because it is an "affirmation of fact or written promise made in connection with the sale of" the product, "which relates to the nature of the material . . . and affirms or promises that such material . . . is defect free or will meet a specified level of performance . . . ." 15 U.S.C. § 2301(6)(A).

66. As set forth herein, Equate does not provide "clinical strength," "high absorption," or "3 times better absorption," as warranted.

67. Although Equate does not meet the "clinical strength"/"high absorption"/"3 times better absorption" specification, WAL-MART has so far failed to refund Equate's purchasers their money.

68. By reason of WAL-MART's breach of these express written warranties, WAL-MART has violated the statutory rights due plaintiff and the class members pursuant to the Magnuson-Moss Warranty Act, thereby damaging plaintiffs and the class members. 15 U.S.C. §§ 2301 *et seq.*

69. Plaintiffs and the class were injured as a direct and proximate result of WAL-MART's breach because: (a) they would not have purchased Equate on the same terms if they had known the true facts concerning its purported "better absorption"; (b) they paid a price premium due to WAL-MART's misleading representations that Equate provides increased absorption, and (c) Equate does not perform as promised.

70. Plaintiff, on behalf of herself and the class members, seeks damages, equitable relief, and attorney's fees and costs pursuant to 15 U.S.C. §§2310(d)(1),(2).

SECOND CAUSE OF ACTION

VIOLATIONS OF THE ARKANSAS DECEPTIVE TRADE PRACTICES ACT, ARK. CODE ANN. §§ 4-88-101 *ET SEQ.*

(By the Nationwide Class)

71. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

72. The business practices of WAL-MART constitute the sale of "goods" within the meaning of Ark. Code Ann. § 4-88-102(3).

73. The same business practices constitute business, commerce, or trade within the meaning of Ark. Code Ann. § 4-88-107.

74. The conduct engaged in by WAL-MART constitutes deceptive and unconscionable practices prohibited by the Arkansas Deceptive Trade Practices Act. The prohibited practices in which WAL-MART has engaged include, but are not necessarily limited to, violations of Ark. Code Ann. §§ 4-88-107(a)(1)-(3), and (10).

75. Pursuant to Ark. Code Ann. § 4-88-113(f), plaintiff seeks recovery of her and the class members' actual damages, together with her reasonable attorney's fees in investigating and prosecuting this action.

THIRD CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §§ 17200 *ET SEQ.*

(By the California Subclass)

76. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

77. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice," Cal. Bus. & Prof. Code § 17200.

Fraudulent

78. WAL-MART's claim that Equate provides "clinical strength," "high absorption," and "3 times better absorption" than competitors, and that it generally supports heart health and benefits statin users, is false and misleading, and fraudulent under the UCL, because Equate is only partially effective, as detailed herein. Thus, Equate's label is likely to deceive a reasonable consumer.

79. WAL-MART's omissions of material fact as set forth herein are also prohibited by the UCL's "fraudulent" prong.

Unfair

80. WAL-MART's conduct with respect to the labeling, advertising, and sale of Equate was unfair because its conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

81. WAL-MART's conduct with respect to the labeling, advertising, and sale of Equate was also unfair because it violated public policy as declared by specific constitutional, statutory or regulatory provisions, including the False Advertising Law.

82. WAL-MART's conduct with respect to the labeling, advertising, and sale of Equate was also unfair because the consumer injury was substantial, not outweighed by benefits to consumers or competition, and not one consumers themselves could reasonably have avoided.

Unlawful

83. The acts alleged herein are "unlawful" under the UCL in that they violate the following laws:

- The Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2103 *et seq.*;
- The Lanham Act, 15 U.S.C. §§ 1501 *et seq.*;
- The Arkansas Deceptive Trade Practices Act, Ark. Code Ann. §§ 4-88-101 *et seq.*;
- The False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*; and
- The Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*

* * *

84. In accordance with Cal. Bus. & Prof. Code § 17203, plaintiff seeks an order enjoining WAL-MART from continuing to conduct business through unlawful, unfair, or fraudulent acts and practices, and to commence a corrective advertising campaign.

85. On behalf of herself and the subclass, plaintiff also seeks an order for the restitution of all monies from the sale of Equate, which were unjustly acquired through acts of unlawful, unfair, or fraudulent competition.

FOURTH CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA FALSE ADVERTISING LAW, CAL. BUS. & PROF. CODE §§ 17500 *ET SEQ.*

(By the California Subclass)

86. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

87. The FAL prohibits any statement in connection with the sale of goods "which is untrue or misleading," Cal. Bus. & Prof. Code § 17500.

88. WAL-MART's claim that Ultra provides "clinical strength," "high absorption," and "3 times better absorption" than competing products, and that it generally supports heart health and benefits statin users, is untrue or misleading in that Equate does not sufficiently dissolve for effectiveness.

89. WAL-MART knew, or reasonably should have known, that the claims were untrue or misleading.

90. Plaintiff and members of the subclass are entitled to injunctive and equitable relief, and restitution in the amount they spent on the WAL-MART Equate.

FIFTH CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA CONSUMERS LEGAL REMEDIES ACT, CAL. CIV. CODE §§ 1750 *ET SEQ.*

(By the California Subclass)

91. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

92. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

93. CVS's policies, acts, and practices were designed to, and did, result in the purchase and use of the products primarily for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:

a. § 1770(a)(2): misrepresenting the source, sponsorship, approval, or certification of goods or services;

b. § 1770(a)(3): misrepresenting the affiliation, connection, or association with, or certification by, another;

c. § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have;

d. § 1770(a)(6): representing that goods are original or new if they have deteriorated unreasonably or are altered, reconditioned, reclaimed, used, or secondhand;

e. § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;

f. § 1770(a)(8): disparaging the goods, services, or business of another by false or misleading representation of fact;

g. § 1770(a)(9): advertising goods with intent not to sell them as advertised; and

h. § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

94. As a result, plaintiff and the subclass members have suffered irreparable harm and are entitled to injunctive relief.

95. In compliance with Cal. Civ. Code § 1780(d), plaintiff's affidavit of venue is filed concurrently herewith, attached to the end of this Complaint.

96. In compliance with Civ. Code § 1782, plaintiff has sent written notice to WAL-MART of her claims, which both WAL-MART and its registered agent received on August 26, 2013.

97. Although plaintiff does not currently seek damages for her claims under the CLRA, if WAL-MART refuses to remedy the violation within 30 days of receiving the notice letter, plaintiff may thereafter amend this Complaint to seek damages.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(By the Nationwide Class)

98. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

99. In selling Equate to plaintiff and the class members, WAL-MART made an affirmation of fact or promise that Equate provides "clinical strength," "high absorption," and "3 times better absorption" than competing products. This affirmation of fact, promise or description formed part of the basis of the bargain. WAL-MART thus expressly warranted the goods sold.

100. Equate was in the defective condition alleged herein, causing the breach of warranty, when it left WAL-MART, e.g., when plaintiff and other consumers purchased it. This was the proximate cause of plaintiff's injuries and those of the class.

101. Prior to filing the lawsuit, plaintiff, on behalf of herself and the class, gave WAL-MART notice of the breach.

102. Plaintiff, on behalf of herself and the class, seeks actual damages for WAL-MART's breach of warranty.

SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By the Nationwide Class)

103. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

104. In selling Equate to plaintiff and the class members, WAL-MART impliedly warranted that the goods sold were merchantable, but Equate does not provide the minimum level of CoQ10 required and fails to adequately dissolve.

105. Plaintiff and the class members suffered injury as a result of WAL-MART's breach in that they paid money for a product that does not adequately dissolve or provide the benefit advertised.

106. Prior to filing the lawsuit, plaintiff, on behalf of herself and the class, gave WAL-MART notice of the breach.

107. Plaintiff, on behalf of herself and the class, seeks actual damages for WAL-MART's breach of warranty.

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF FITNESS

(By the Nationwide Class)

108. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

109. In selling Equate to plaintiff and the class members, WAL-MART impliedly warranted the goods sold were fit for their particular purpose, e.g., supplementing the body's natural Coenzyme Q10 production.

110. WAL-MART breached the warranty in that Equate did not provide the minimum level of CoQ10 required, and failed to adequately dissolve.

111. Plaintiff and the class members suffered injury as a result of WAL-MART's breach in that they paid money for an product that did not adequately dissolve to be fit for its purpose.

112. Prior to filing the lawsuit, plaintiff, on behalf of herself and the class, gave WAL-MART notice of the breach.

113. Plaintiff, on behalf of herself and the class, seeks actual damages for WAL-MART's breach of warranty.

NINTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY, CAL. COMM. CODE § 2313

(By the California Subclass)

114. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

115. There was a sale of goods from WAL-MART to plaintiff and the subclass members.

116. WAL-MART made an affirmation of fact or promise that Equate provides "clinical strength," "high absorption," and "3 times better absorption" than competing products. This affirmation of fact, promise or description formed part of the basis of the bargain. WAL-MART thus expressly warranted the goods sold.

117. WAL-MART breached the warranty in that Equate does not provide the minimum amount of CoQ10 required and fails to adequately dissolve.

118. Plaintiff and the subclass members suffered injury as a result of WAL-MART's breach in that they paid money for an ineffective product.

119. Prior to filing this lawsuit, plaintiff, on behalf of herself and the subclass, gave WAL-MART notice of the breach.

120. Plaintiff, on behalf of herself and the subclass, seeks actual damages for WAL-MART's breach of warranty.

TENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY, CAL. COMM. CODE § 2313(1)

(By the California Subclass)

121. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

122. "Unless excluded or modified . . . a warranty that goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Cal. Comm. Code § 2314(1).

123. There was a sale of goods from WAL-MART to plaintiff and the subclass members.

124. WAL-MART impliedly warranted the goods sold were merchantable.

125. WAL-MART breached the warranty in that Equate does not provide the minimum amount of CoQ10 required, nor adequately dissolve.

126. Plaintiff and the subclass members suffered injury as a result of WAL-MART's breach in that they paid money for a product that does not adequately dissolve or provide the benefit advertised.

127. Prior to filing this lawsuit, plaintiff, on behalf of herself and the subclass, gave WAL-MART notice of the breach.

128. Plaintiff, on behalf of herself and the subclass, seeks actual damages for WAL-MART's breach of warranty.

ELEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF FITNESS, CAL. COMM. CODE § 2315

(By the California Subclass)

129. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

130. "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Cal. Comm. Code § 2315.

131. There was a sale of goods from WAL-MART to plaintiff and the subclass members.

132. WAL-MART impliedly warranted the goods sold were fit for their particular purpose, e.g., supplementing the body's natural Coenzyme Q10 production.

133. WAL-MART breached the warranty in that Equate was ineffective.

134. Plaintiff and the subclass members suffered injury as a result of WAL-MART's breach in that they paid money for an product that did not provide sufficient CoQ10, nor adequately dissolve to be fit for its purpose.

135. Prior to filing this lawsuit, plaintiff, on behalf of herself and the subclass, gave WAL-MART notice of the breach.

136. Plaintiff, on behalf of herself and the subclass, seeks actual damages for WAL-MART's breach of warranty.

PRAYER FOR RELIEF

137. Wherefore, Plaintiff, on behalf of herself, all others similarly situated and the general public, prays for judgment against WAL-MART as to each and every cause of action, and the following remedies:

A. An Order certifying this as a class action and appointing plaintiff and her counsel to represent the class and subclass;

B. An Order enjoining WAL-MART from selling Equate so long as the product fails to provide the USP-minimum level of CoQ10 or fails to adequately dissolve under the applicable USP standards;

C. An Order enjoining WAL-MART from labeling, advertising, or packaging Equate with any claim of "clinical strength," or "higher" or "better" absorption, unless WAL-MART has sufficient scientific evidence to make the claim;

D. An Order compelling WAL-MART to conduct a corrective advertising campaign to inform the public that Equate did not adequately dissolve or provide the advertised benefits;

E. An Order requiring WAL-MART to disgorge or return all monies, revenues, and profits obtained by means of any wrongful or unlawful act or practice;

F. An Order requiring WAL-MART to pay all actual and statutory damages permitted under the causes of action alleged herein;

G. An Order requiring WAL-MART to pay restitution to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising, or a violation of the UCL, FAL or CLRA, plus pre- and post-judgment interest thereon;

H. Costs, expenses, and reasonable attorneys' fees; and

I. Any other and further relief the Court deems necessary, just, or proper.

Dated: September 3, 2013

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Counsel for Plaintiff and the Proposed Classes

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

THAMAR SANTISTEBAN CORTINA, on behalf of herself, all others similarly situated and the general public,

Plaintiff,

v.

WAL-MART, INC.,

Defendant.

CONSUMERS LEGAL REMEDIES ACT VENUE AFFIDAVIT [CCP § 1780(d)]

I, Thamar Santisteban Cortina, declare as follows:

1. I am the Plaintiff in this action. I make this affidavit as required by California Civil Code § 1780(d).

2. The Complaint in this action is filed in a proper place for the trial of this action because defendant is doing business in this county.

3. The Complaint in this action is further filed in a proper place for the trial of this action because the transactions that are the subject of the action occurred in this county.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 3rd day of September, 2013, at Bonita, California.

Thamar Santisteban Cortina

CIVIL COVER SHEET

'13CV2054 JAH DHB

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Thamar Santisteban Cortina

(b) County of Residence of First Listed Plaintiff San Diego
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Jack Fitzgerald, The Law Office of Jack Fitzgerald, PC, 2850 4th Ave, Ste. 11, San Diego, CA 92103, (619) 692-3840

DEFENDANTS

Wal-Mart Stores, Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
15 U.S.C. §§ 2301 et seq. (Magnuson-Moss Warranty Act)

Brief description of cause:
Breach of Warranties & False Advertising

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P. **DEMAND $**

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY
(See instructions):

JUDGE DOCKET NUMBER

DATE
09/03/2013

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

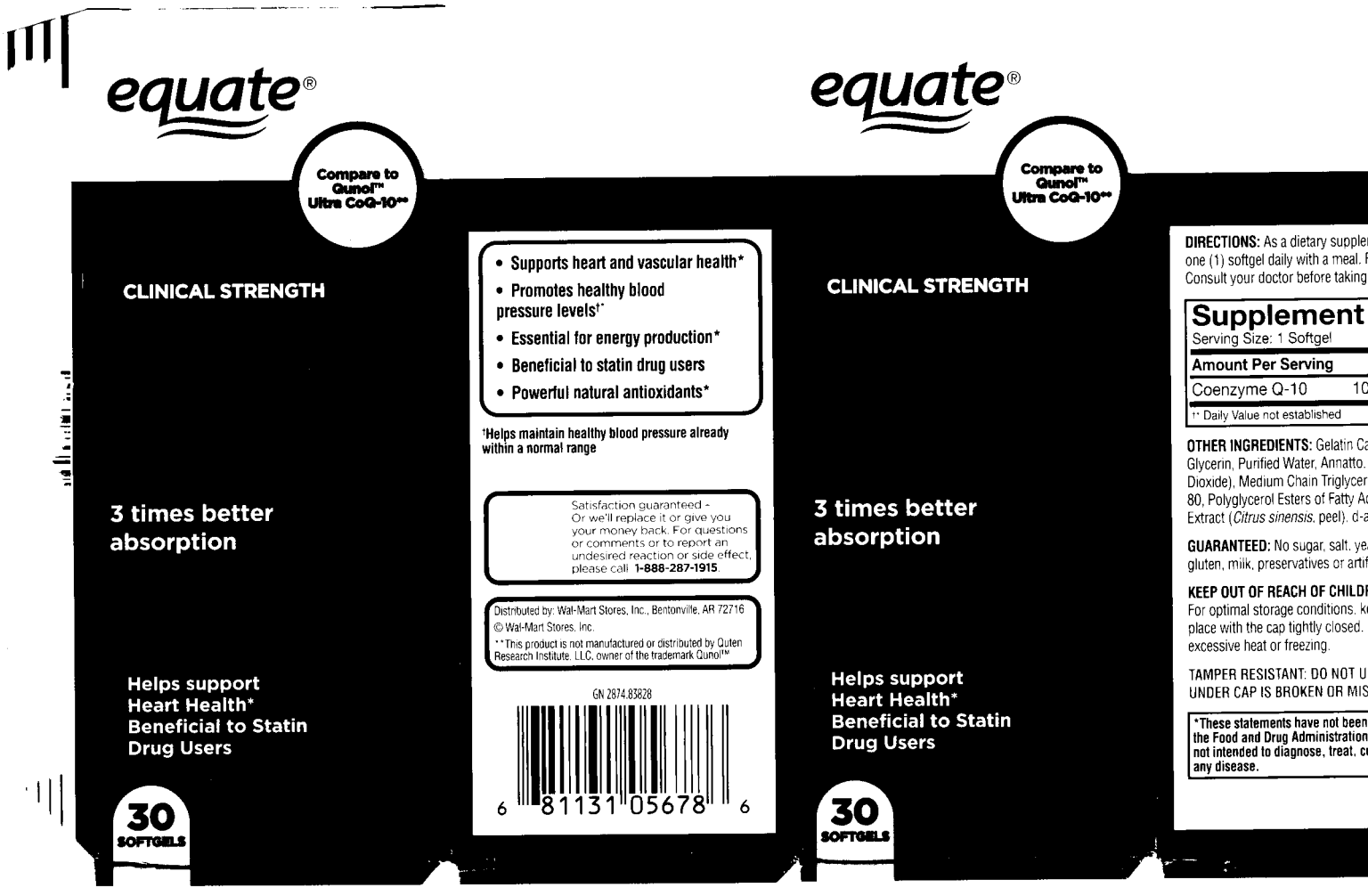
equate®

CLINICAL STRENGTH

High Absorption

Co Q-10

100 mg



LOT C13NM29
EXP 01/15

Mobile phase, System suitability solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of impurities in the portion of Ubidecarenone taken:

$$\text{Result} = (r_{T1}/r_{T2}) \times 100$$

r_{T1} = sum of all peak responses, other than that for ubidecarenone

r_{T2} = sum of all peak responses

Acceptance criteria: NMT 1.0%

Procedure 2: Ubidecarenone (2*Z*)-Isomer and Related Impurities

Mobile phase: *n*-Hexane and ethyl acetate (97:3)

System suitability solution: 1 mg/mL of USP Ubidecarenone for System Suitability RS in *n*-hexane

Sample solution: 1 mg/mL of Ubidecarenone in *n*-hexane

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm × 25-cm; packing L3

Flow rate: 2 mL/min

Injection size: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for ubidecarenone (2*Z*)-isomer and ubidecarenone are about 0.85 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the ubidecarenone (2*Z*)-isomer and ubidecarenone

Analysis

Sample: *Sample solution*

Calculate the percentage of impurities in the portion of Ubidecarenone taken:

$$\text{Result} = (r_{T1}/r_{T2}) \times 100$$

r_{T1} = sum of all peak responses, other than that for ubidecarenone

r_{T2} = sum of all peak responses

Acceptance criteria: NMT 1.0%

Total impurities: NMT 1.5%, obtained from *Chromatographic Purity Procedures 1* and *2*

SPECIFIC TESTS

- **WATER DETERMINATION,** *Method I* ⟨921⟩: NMT 0.2%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.
- **USP REFERENCE STANDARDS** ⟨11⟩

USP Ubidecarenone RS

USP Ubidecarenone Related Compound A RS [coenzyme Q_9]

USP Ubidecarenone for System Suitability RS

Ubidecarenone Capsules

DEFINITION

Ubidecarenone Capsules contain NLT 90.0% and NMT 115.0% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$).

IDENTIFICATION

- **A.** The retention time of the major peak of either *Sample solution 1* or *Sample solution 2* corresponds to that of the *Standard solution*, as obtained in the *Procedure* for *Strength*.

STRENGTH

- **PROCEDURE**

[NOTE—Conduct this test promptly with minimum exposure to actinic light.]

Solvent: *n*-Hexane and dehydrated alcohol (5:2)

Mobile phase: Acetonitrile, tetrahydrofuran, and water (55:40:5)

Standard stock solution: 1.0 mg/mL of USP Ubidecarenone RS in *Solvent*

Standard solution: 40 µg/mL in dehydrated alcohol, from the *Standard stock solution*

System suitability stock solution: 1.0 mg/mL of USP Ubidecarenone Related Compound A RS in *Solvent*. Dilute a portion of this solution with dehydrated alcohol to obtain a concentration of 40 µg/mL.

System suitability solution: *Standard solution* and *System suitability stock solution* (1:1)

Sample solution 1 (for soft gelatin Capsules): Open a number of Capsules equivalent to 200 mg of ubidecarenone, quantitatively transfer the shells and contents to a container, add 100 mL of *Solvent*, and shake by mechanical means for 30 min. Using small portions of *Solvent*, quantitatively transfer this mixture to a 200-mL volumetric flask, and dilute with *Solvent* to volume. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Sample solution 2 (for hard gelatin Capsules): Empty and thoroughly mix the contents of NLT 20 Capsules. Transfer a portion of the powder, equivalent to 100 mg of ubidecarenone, to a 100-mL volumetric flask, add 60 mL of *Solvent*, and shake by mechanical means for 30 min. Dilute with *Solvent* to volume. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 8-mm × 10-cm; packing L1

Flow rate: 2.5 mL/min

Injection size: 15 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

Suitability requirements

Resolution: NLT 2.5 between ubidecarenone and ubidecarenone related compound A, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2.0% for ubidecarenone, *Standard solution*

Analysis

Samples: *Sample solution 1* or *Sample solution 2*, and *Standard solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of ubidecarenone from *Sample solution 1* or *Sample solution 2*

r_S = peak area of ubidecarenone from the *Standard solution*

C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of ubidecarenone in *Sample solution 1* or *Sample solution 2* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- **DISINTEGRATION AND DISSOLUTION ⟨2040⟩:** Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Capsules labeled to contain a water-soluble form of ubidecarenone meet the requirements for the test for *Dissolution*, as follows.

Medium: Water; 500 mL
Apparatus 2: 75 rpm
Time: 60 min
Standard solution: Dissolve 25 mg of USP Ubidecarenone RS in 1 mL of ethyl ether, and dilute with alcohol to obtain a concentration of 2.5 µg/mL. [NOTE—Use a freshly prepared solution only.]
Sample solution: Dilute with alcohol a volume of the solution under test, previously passed through a suitable filter of 0.45-µm pore size, to obtain a concentration of 2.5 µg/mL of ubidecarenone.
Mobile phase and **Chromatographic system:** Proceed as directed in the *Procedure* for *Strength*, except for *Injection size*.
Injection size: 100 µL
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times V \times D/L) \times 100$$

r_U = peak area of ubidecarenone from the *Sample solution*
r_S = peak area of ubidecarenone from the *Standard solution*
C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)
V = volume of *Medium*, 500 mL
D = dilution factor for the *Sample solution*
L = label claim (mg/Capsule)

Tolerances: NLT 75% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) is dissolved.

SPECIFIC TESTS

- **WEIGHT VARIATION ⟨2091⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **LABELING:** Where the product contains a water-soluble form of ubidecarenone, this is so stated on the label.
- **USP REFERENCE STANDARDS ⟨11⟩**
USP Ubidecarenone RS
USP Ubidecarenone Related Compound A RS
Coenzyme Q_9.

Ubidecarenone Tablets

DEFINITION

Ubidecarenone Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Procedure* for *Strength*.

STRENGTH

- **PROCEDURE**

[NOTE—Conduct this test promptly with minimum exposure to actinic light.]
Solvent: *n*-Hexane and dehydrated alcohol (5:2)
Mobile phase: Acetonitrile, tetrahydrofuran, and water (11:8:1)
Standard stock solution: 1.0 mg/mL of USP Ubidecarenone RS in *Solvent*
Standard solution: 40 µg/mL from *Standard stock solution* in dehydrated alcohol
System suitability stock solution: 1.0 mg/mL of USP Ubidecarenone Related Compound A RS in *Solvent*. Dilute a portion of this solution with dehydrated alcohol to obtain a concentration of 40 µg/mL.
System suitability solution: *Standard solution* and *System suitability stock solution* (1:1)
Sample stock solution: Weigh and finely powder NLT 20 Tablets. Transfer a quantity of powder, equivalent to about 100 mg of ubidecarenone, to a 100-mL volumetric flask, add 60 mL of *Solvent*, and shake by mechanical means for 30 min. Dilute with *Solvent* to volume, and mix. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, and add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol. Dilute with alcohol to volume, and mix.
Sample solution: Centrifuge a portion of *Sample stock solution*, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 280 nm
Column: 8-mm × 10-cm; packing L1
Flow rate: 2.5 mL/min
Injection size: 15 µL
System suitability
Samples: *Standard solution* and *System suitability solution*
Suitability requirements
Resolution: NLT 2.5 between ubidecarenone and ubidecarenone related compound A, *System suitability solution*
Tailing factor: NMT 1.5, *Standard solution*
Relative standard deviation: NMT 2.0% for ubidecarenone, *Standard solution*
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of ubidecarenone from the *Sample solution*
r_S = peak area of ubidecarenone from the *Standard solution*
C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of ubidecarenone in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- **DISINTEGRATION AND DISSOLUTION ⟨2040⟩:** Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Tablets labeled to contain a water-soluble form of ubidecarenone meet the requirements for the test for *Dissolution*, as follows.

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⟨2040⟩ DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS

INTRODUCTION

This general chapter is provided to determine compliance with the disintegration and dissolution standards for dietary supplements where stated in the individual monographs.

For the purposes of this chapter, dietary supplement dosage forms have been divided into three categories: *Vitamin–Mineral Dosage Forms, Botanical Dosage Forms,* and *Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms. Vitamin–Mineral Dosage Forms* includes articles prepared with vitamins, minerals, or combinations of these dietary ingredients (e.g., USP dietary supplements *Class I* to *Class VI*, described below). *Botanical Dosage Forms* comprises formulations containing ingredients of botanical origin, including plant materials and extracts. *Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms* encompasses dietary supplements formulated with lawfully recognized dietary ingredients that are different from those pertaining to the two foregoing categories (e.g., amino acids, chondroitin, and glucosamine).

Where a dietary supplement represents a combination of the categories mentioned above, and there is a difference between the requirements for the individual categories, the more stringent requirement applies.

Dissolution testing as described in this chapter is a quality-control tool to enable the performance of dietary supplements to be routinely assessed.

DISINTEGRATION

This test is provided to determine whether dietary supplement tablets or capsules disintegrate within the prescribed time when placed in a liquid medium at the experimental conditions presented below. Compliance with the limits on *Disintegration* stated in the individual monographs for dietary supplements is required except where the label states that the products are intended for use as troches, are to be chewed, or are designed as extended-release dosage forms. Dietary supplements claiming to be extended-release dosage forms must comply with standards other than disintegration to verify that the release of the dietary ingredients from the dosage form is for a defined period of time. Dietary supplements claiming to be extended-release dosage forms shall not be labeled as in compliance with USP unless a USP monograph exists for such product. Determine the type of units under test from the labeling and from observation, and apply the appropriate procedure to 6 or more units.

For purposes of this test, disintegration does not imply complete solution of the unit or even of its active constituent. Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the disk, if used, is a soft mass having no palpably firm core.

Apparatus

Apparatus A—Use the *Apparatus* described under *Disintegration* ⟨701⟩ for tablets or capsules that are not greater than 18 mm long. For larger tablets or capsules, use *Apparatus B.*

Apparatus B—The apparatus[1] consists of a basket-rack assembly, a 1000-mL, low-form beaker for the immersion fluid, a thermostatic arrangement for heating the fluid between 35° and 39°, and a device for raising and lowering the basket in the immersion fluid at a constant frequency rate between 29 and 32 cycles per minute through a distance of not less than 53 mm and not more than 57 mm. The volume of the fluid in the vessel is such that at the highest point of the upward stroke the wire mesh remains at least 15 mm below the surface of the fluid and descends to not less than 25 mm from the bottom of the vessel on the downward stroke. At no time should the top of the basket-rack assembly become submerged. The time required for the upward stroke is equal to the time required for the downward stroke, and the change in stroke direction is a smooth transition rather than an abrupt reversal of motion. The basket-rack assembly moves vertically along its axis. There is no appreciable horizontal motion or movement of the axis from the vertical.

Basket-Rack Assembly—The basket-rack assembly consists of three open-ended transparent tubes, each 77.5 ± 2.5 mm long and having an inside diameter of 32.0 to 34.6 mm and a wall 2.0 to 3.0 mm thick; the tubes are held in a vertical position by two plastic plates, each about 97 mm in diameter and 7.5 to 10.5 mm in thickness, with three holes, each about 33 to 34 mm in diameter, equidistant from the center of the plate and equally spaced from one another. Attached to the under surface of the lower plate is 10-mesh No. 23 (0.025-inch) W. and M. gauge woven stainless-steel wire cloth having a plain square weave. The parts of the apparatus are assembled and rigidly held by means of three bolts passing through the two plastic plates. A suitable means is provided to suspend the basket-rack assembly from the raising and lowering device using a point on its axis.

The design of the basket-rack assembly may be varied somewhat provided the specifications for the glass tubes and the screen mesh size are maintained.

Disks—Each tube is provided with a perforated cylindrical disk 15.3 ± 0.15 mm thick and 31.4 ± 0.13 mm in diameter. The disk is made of a suitable, transparent plastic material having a specific gravity of between 1.18 and 1.20. Seven 3.15 ± 0.1-mm holes extend between the ends of the cylinder, one of the holes being through the cylinder axis and the others parallel with it and equally spaced on a 4.2 ± 0.1-mm radius from it. All surfaces of the disk are smooth.[2]

Procedure

Uncoated Tablets—Place 1 tablet in each of the tubes of the basket and, if prescribed, add a disk to each tube. Operate the apparatus, using water or the specified medium as the immersion fluid, maintained at 37 ± 2°. At the end of 30 minutes, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Plain Coated Tablets—Place 1 tablet in each of the tubes of the basket and, if the tablet has a soluble external sugar coating, immerse the basket in water at room temperature for 5 minutes. Then, if prescribed, add a disk to each tube, and operate the apparatus, using water or the specified medium as the immersion fluid, maintained at 37 ± 2°. At the end of 30 minutes, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Delayed-Release (Enteric-Coated) Tablets—Place 1 tablet in each of the six tubes of the basket, and if the tablet has a soluble external sugar coating, immerse the basket in water at room temperature for 5 minutes. Then operate the apparatus using simulated gastric fluid TS maintained at 37 ± 2° as the immersion fluid. After

[1] An apparatus and disks meeting these specifications are available from Varian Inc., 13000 Weston Parkway, Cary, NC 27513, or from laboratory supply houses.

[2] The use of automatic detection employing modified disks is permitted where the use of disks is specified or allowed. Such disks must comply with the requirements for density and dimensions given in this chapter.

1 hour of operation in simulated gastric fluid TS, lift the basket from the fluid, and observe the tablets: the tablets show no evidence of disintegration, cracking, or softening. Operate the apparatus, using simulated intestinal fluid TS, maintained at 37 ± 2°, as the immersion fluid for the time specified in the monograph. Lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Buccal Tablets—Apply the test for *Uncoated Tablets*. After 4 hours, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Sublingual Tablets—Apply the test for *Uncoated Tablets*. At the end of the time limit specified in the individual monograph, all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Hard Shell Capsules—Apply the test for *Uncoated Tablets,* using as the immersion fluid, maintained at 37 ± 2°, a 0.05 M acetate buffer prepared by mixing 2.99 g of sodium acetate trihydrate and 1.66 mL of glacial acetic acid with water to obtain a 1000-mL solution having a pH of 4.50 ± 0.05. Attach a removable wire cloth, as described under *Basket-Rack Assembly,* to the surface of the upper plate of the basket-rack assembly. At the end of 30 minutes, lift the basket from the fluid, and observe the capsules: all of the capsules disintegrate except for fragments from the capsule shell. If 1 or 2 capsules fail to disintegrate completely, repeat the test on 12 additional capsules: not fewer than 16 of the total of 18 capsules tested disintegrate completely.

Soft Shell Capsules—Proceed as directed under *Rupture Test for Soft Shell Capsules.*

Use of Disks—

VITAMIN–MINERAL DOSAGE FORMS—Add a disk to each tube unless otherwise specified in the individual monograph.

BOTANICAL DOSAGE FORMS—Omit the use of disks unless otherwise specified in the individual monograph.

DIETARY SUPPLEMENTS OTHER THAN VITAMIN–MINERAL AND BOTANICAL DOSAGE FORMS—Omit the use of disks unless otherwise specified in the individual monograph.

NOTE—The use of disks for enteric-coated tablets is not permitted.

RUPTURE TEST FOR SOFT SHELL CAPSULES

Medium: water; 500 mL.

Apparatus—Use *Apparatus 2* as described under *Dissolution* ⟨711⟩, operating at 50 rpm.

Time: 15 minutes.

Procedure—Place 1 capsule in each vessel, and allow the capsule to sink to the bottom of the vessel before starting rotation of the blade. Observe the capsules, and record the time taken for each capsule shell to rupture.

Tolerances—The requirements are met if all of the capsules tested rupture in not more than 15 minutes. If 1 or 2 of the capsules rupture in more than 15 but not more than 30 minutes, repeat the test on 12 additional capsules: not more than 2 of the total of 18 capsules tested rupture in more than 15 but not more than 30 minutes.

Change to read:

DISSOLUTION

This test is provided to determine compliance with the *Dissolution* requirements where stated in the individual monograph for dietary supplements, except where the label states that tablets are to be chewed.

See *Dissolution* ⟨711⟩ for description of apparatus used, *Apparatus Suitability Test,* and other related information. Of the types of apparatus described in ⟨711⟩, use the one specified in the individual monograph.

•Soft gelatin capsule preparations of dietary supplements meet the requirements for *Disintegration.*

Official until May 1, 2010

• (RB 1-May-2009)

For hard or soft gelatin capsules and gelatin-coated tablets that do not conform to the dissolution specification, repeat the test as follows. Where water or a medium with a pH of less than 6.8 is specified as the *Medium* in the individual monograph, the same *Medium* specified may be used with the addition of purified pepsin that results in an activity of 750,000 Units or less per 1000 mL. For media with a pH of 6.8 or greater, pancreatin can be added to produce not more than 1750 USP Units of protease activity per 1000 mL.

This nonspecific dissolution is intended to be diagnostic of known technological problems that may arise as a result of coatings, lubricants, disintegrants, and other substances inherent in the manufacturing process. For dosage forms containing botanical extracts, this dissolution measurement allows an assessment of the extent of decomposition of the extract to polymeric or other nondissoluble compounds that may have been produced by excessive drying or other manipulations involved in the manufacture of botanical extracts. The operative assumption inherent in this procedure is that if the index or marker compound(s) or the extract is demonstrated to have dissolved within the time frame and under conditions specified, the dosage form does not suffer from any of the above formulation or manufacturing related problems.

Vitamin–Mineral Dosage Forms

All dietary supplements belonging to USP *Classes II* to *VI,* prepared as tablets or capsules, are subject to the dissolution test and criteria described in this chapter for folic acid (if present) and for index vitamins and index minerals. This test is required because of the importance of the relationship between folate deficiency and the risk of neural tube defects. The accompanying table lists the dissolution requirements for the individual USP classes of dietary supplements. *Class I* dietary supplements are combinations of oil-soluble vitamins for which dissolution standards are not established; hence, dissolution requirements do not apply to the oil-soluble vitamins contained in formulations belonging to *Class IV* or *Class V.* Vitamin–mineral combinations that may not be strictly covered by USP *Class I* to *Class VI* are subject to the dissolution test and criteria specified in the individual monographs.

Dietary Supplements—Vitamin–Mineral Dosage Forms

USP Class	Combination of Vitamins or Minerals Present	Dissolution Requirement
I	Oil-Soluble Vitamins	not applicable
II	Water-Soluble Vitamins	one index vitamin; folic acid (if present)
III	Water-Soluble Vitamins with Minerals	one index vitamin and one index element; folic acid (if present)
IV	Oil- and Water-Soluble Vitamins	one index water-soluble vitamin; folic acid (if present)
V	Oil- and Water-Soluble Vitamins with Minerals	one index water-soluble vitamin and one index element; folic acid (if present)
VI	Minerals	one index element

Unless otherwise stated in the individual monograph, test 6 dosage units for dissolution as directed under *Dissolution* ⟨711⟩.

DISSOLUTION CONDITIONS FOR FOLIC ACID

NOTE—Perform this test under light conditions that minimize photo degradation.

Medium: water; 900 mL. If the units tested do not meet the requirements for dissolution in water, test 6 additional dosage units for dissolution in a medium of 900 mL of 0.05 M pH 6.0 citrate buffer solution, prepared by mixing 9.5 mL of 0.1 M citric acid monohydrate and 40.5 mL of 0.1 M sodium citrate dihydrate in a 100-mL volumetric flask, diluting with water to volume, mixing, and adjusting to a pH of 6.0 by using either 0.1 M hydrochloric acid or 0.1 M sodium hydroxide solution.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

NOTE—Compliance with the dissolution requirements for folic acid does not exempt the product from dissolution testing of the pertinent index vitamin or the corresponding index mineral.

DISSOLUTION CONDITIONS FOR INDEX VITAMINS AND INDEX MINERALS

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

For formulations containing 25 mg or more of the index vitamin, riboflavin, use the following conditions:

Medium: 0.1 N hydrochloric acid; 1800 mL.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

NOTE—Compliance with dissolution requirements for the pertinent index vitamin or index mineral does not exempt the product from dissolution testing of folic acid, if present.

SELECTION OF INDEX VITAMINS AND INDEX ELEMENTS

Compliance with the dissolution requirements for dietary supplements representing combinations of water-soluble vitamins (*Water-Soluble Vitamins Capsules* and *Water-Soluble Vitamins Tablets*) and combinations of oil- and water-soluble vitamins (*Oil- and Water-Soluble Vitamins Capsules* and *Oil- and Water-Soluble Vitamins Tablets*) is determined by measuring the dissolution of a single index vitamin from the water-soluble vitamins present. Riboflavin is the index vitamin when present in the formulation. For formulations that do not contain riboflavin, pyridoxine is the index vitamin. If neither riboflavin nor pyridoxine is present in the formulation, the index vitamin is niacinamide (or niacin), and in the absence of niacinamide (or niacin), the index vitamin is thiamine. If none of the above four water-soluble vitamins is present in the formulation, the index vitamin is ascorbic acid.

Compliance with the dissolution requirements for dietary supplements representing combinations of minerals (*Minerals Capsules* and *Minerals Tablets*) is determined by measuring the dissolution of only one index element. Iron is the index element when present in the formulation. For formulations that do not contain iron, the index element is calcium. If neither iron nor calcium is present, the index element is zinc, and in the absence of all three of these elements, magnesium is the index element.

Compliance with dissolution requirements for dietary supplements representing combinations of water-soluble vitamins and minerals (*Water-Soluble Vitamins with Minerals Capsules* and *Water-Soluble Vitamins with Minerals Tablets*) and combinations of oil- and water-soluble vitamins and minerals (*Oil- and Water-Soluble Vitamins with Minerals Capsules* and *Oil- and Water-Soluble Vitamins with Minerals Tablets*) is determined by measuring the dissolution of one index water-soluble vitamin and one index element, designated according to the respective hierarchies described above.

PROCEDURES

In the following procedures, combine equal volumes of the filtered solutions of the 6 individual specimens withdrawn, and determine the amount of folic acid or the index vitamin or element dissolved, based on the average of 6 units tested. Make any necessary modifications including concentration of the analyte in the volume of test solution taken. Use the *Medium* for preparation of the Standard solution and dilution, if necessary, of the test solution.

Folic Acid—Determine the amount of $C_{19}H_{19}N_7O_6$ dissolved by employing the procedure set forth in the *Assay for folic acid* under *Oil- and Water-Soluble Vitamins with Minerals Tablets*, in comparison with a Standard solution having a known concentration of USP Folic Acid RS in the same *Medium*.

Niacin or Niacinamide, Pyridoxine, Riboflavin, and Thiamine—Determine the amount of the designated index vitamin dissolved by employing the procedure set forth in the *Assay for niacin or niacinamide, pyridoxine, riboflavin, and thiamine* under *Water-Soluble Vitamins Tablets.*

Ascorbic Acid—Determine the amount of $C_6H_8O_6$ dissolved by adding 10 mL of 1.0 N sulfuric acid and 3 mL of starch TS to 100.0 mL of test solution, and titrating immediately with 0.01 N iodine VS. Perform a blank determination, and make any necessary correction.

Iron, Calcium, Magnesium, and Zinc—Determine the amount of the designated index element dissolved by employing the procedure set forth in the appropriate *Assay* under *Minerals Capsules*.

TOLERANCES

The requirements are met if not less than 75% of the labeled content of folic acid and not less than 75% of the labeled content of the index vitamin or the index element from the units tested is dissolved in 1 hour.

Botanical Dosage Forms

Compliance with dissolution requirements necessitates the testing of 6 dosage units individually, or testing 2 or more dosage units in each of the 6 vessels of the dissolution apparatus, and measuring the dissolution of one or more index/marker compound(s) or the extract specified in the individual monograph.

PROCEDURES

Combine equal volumes of the filtered solutions of the 6 or more individual specimens withdrawn, and use the pooled sample as the test solution. Determine the average amount of index or marker compound(s) or the extract dissolved in the pooled sample by the *Procedure* specified in the individual monograph. Make any necessary modifications, including concentration of the analyte in the volume of the test solution taken. Use the *Medium* for preparation of the Standard solution and dilution, if necessary, of the test solution.

INTERPRETATION

Pooled Sample—Unless otherwise specified in the individual monograph, the requirements are met if the quantities of the index or marker compound(s) or the extract dissolved from the pooled sample conform to the accompanying acceptance table. The quantity, Q, is the amount of dissolved index or marker compound(s) or the extract specified in the individual monograph, expressed as a percentage of the labeled content. The 5%, 15%, and 25% values in the acceptance table are percentages of the labeled content so that these values and Q are in the same terms.

Acceptance Table for a Pooled Sample

Stage	Number Tested	Acceptance Criteria
S_1	6	Average amount dissolved is not less than Q + 10%
S_2	6	Average amount dissolved (S_1 + S_2) is equal to or greater than Q + 5%
S_3	12	Average amount dissolved (S_1 + S_2 + S_3) is equal to or greater than Q

Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms

Unless otherwise stated in the individual monographs for dietary supplement dosage forms in this category, compliance requires the testing of 6 individual units, measuring the dissolution of the dietary ingredient as the average of the 6 units tested.

PROCEDURES

Combine equal volumes of the filtered solutions of the 6 specimens withdrawn, and use the pooled sample as the test solution. Determine the average amount of dietary ingredient dissolved in the pooled sample by the *Procedure* specified in the individual monograph. Make any necessary modifications, including concentration of the analyte in the volume of the test solution taken. Use the *Medium* for preparation of the Standard solution and for dilution, if necessary, of the test solution.

TOLERANCES

Because of the diversity of chemical characteristics and solubilities of dietary ingredients pertaining to this category, general tolerances cannot be established. See individual monographs for *Tolerances*.

COVANCE

Report Number:	**852626-0**
Report Date:	**12-Aug-2013**
Report Status:	**Final**
Supercedes :	**850236-0**

Certificate of Analysis

[redacted]

Sample Name:	[redacted]	**Covance Sample:**	**2304502**
Project ID	[redacted]-20130802-0001	**Receipt Date**	02-Aug-2013
PO Number	Charge/VISA	**Receipt Condition**	Ambient temperature
Lot Number	Lot 1	**Login Date**	02-Aug-2013
Sample Serving Size	1 Softgel	**Storage Condition**	5 (+/- 3) degrees Celsius
		Number Composited	20
		Online Order	20

Analysis	Result
Calculated Sample Weight	
Entity Weight	0.7441 g
Coenzyme Q10 Dissolution	
Coenzyme Q10	48.2 mg/g
Coenzyme Q10	56.3 mg/g
Coenzyme Q10	54.5 mg/g
Coenzyme Q10	59.2 mg/g
Coenzyme Q10	57.5 mg/g
Coenzyme Q10	56.2 mg/g
Coenzyme Q10	35.9 mg/Serving Size
% of Claim (100 mg/softgel)	35.9 %
Coenzyme Q10	41.9 mg/Serving Size
% of Claim (100 mg/softgel)	41.9 %
Coenzyme Q10	40.6 mg/Serving Size
% of Claim (100 mg/softgel)	40.6 %
Coenzyme Q10	44.1 mg/Serving Size
% of Claim (100 mg/softgel)	44.1 %
Coenzyme Q10	42.8 mg/Serving Size
% of Claim (100 mg/softgel)	42.8 %
Coenzyme Q10	41.8 mg/Serving Size
% of Claim (100 mg/softgel)	41.8 %
Dissolution	
Disintegrated in Specified Time Frame	yes

Method References	Testing Location
Calculated Sample Weight (PREP:8)	**Covance Laboratories - Madison**
Coenzyme Q10 Dissolution (Q10_S:4)	**Covance Laboratories - Madison**

Official Methods of Analysis of AOAC INTERNATIONAL, (2005) 18th ED., AOAC INTERNATIONAL Gaithersburg, MD, USA, Official Method 2008.07.

COVANCE

Report Number:	**852626-0**
Report Date:	**12-Aug-2013**
Report Status:	**Final**
Supercedes :	**850236-0**

Certificate of Analysis

[redacted]

Method References	Testing Location
Dissolution (DISL:4)	**Covance Laboratories - Madison**

United States Pharmacopeia, Thirty Fourth Revision, <2040>, <711>, United States Pharmacopeial Convention, Inc.: Rockville, Maryland (2011).

Client Supplied Method

Testing Location(s)	Released on Behalf of Covance by
Covance Laboratories - Madison	**Lori Ross - Associate Director**

3301 Kinsman Blvd
Madison WI 53704
608-242-2712 x4170

COVANCE

Report Number:	**852627-0**
Report Date:	**12-Aug-2013**
Report Status:	**Final**
Supercedes :	**850237-0**

Certificate of Analysis

[redacted]

Sample Name:	[redacted]	**Covance Sample:**	**2304503**
Project ID	[redacted]-20130802-0001	**Receipt Date**	02-Aug-2013
PO Number	Charge/VISA	**Receipt Condition**	Ambient temperature
Lot Number	Lot 2	**Login Date**	02-Aug-2013
Sample Serving Size	1 Softgel	**Storage Condition**	5 (+/- 3) degrees Celsius
		Number Composited	20
		Online Order	20

Analysis	Result
Calculated Sample Weight	
Entity Weight	0.7435 g
Coenzyme Q10 Dissolution	
Coenzyme Q10	65.5 mg/g
Coenzyme Q10	55.7 mg/g
Coenzyme Q10	56.2 mg/g
Coenzyme Q10	53.9 mg/g
Coenzyme Q10	49.5 mg/g
Coenzyme Q10	52.4 mg/g
Coenzyme Q10	48.7 mg/Serving Size
% of Claim (100 mg/softgel)	48.7 %
Coenzyme Q10	41.4 mg/Serving Size
% of Claim (100 mg/softgel)	41.4 %
Coenzyme Q10	41.8 mg/Serving Size
% of Claim (100 mg/softgel)	41.8 %
Coenzyme Q10	40.1 mg/Serving Size
% of Claim (100 mg/softgel)	40.1 %
Coenzyme Q10	36.8 mg/Serving Size
% of Claim (100 mg/softgel)	36.8 %
Coenzyme Q10	39.0 mg/Serving Size
% of Claim (100 mg/softgel)	39.0 %
Dissolution	
Disintegrated in Specified Time Frame	Yes

Method References	Testing Location
Calculated Sample Weight (PREP:8)	**Covance Laboratories - Madison**
Coenzyme Q10 Dissolution (Q10_S:4)	**Covance Laboratories - Madison**

Official Methods of Analysis of AOAC INTERNATIONAL, (2005) 18th ED., AOAC INTERNATIONAL Gaithersburg, MD, USA, Official Method 2008.07.

COVANCE

Report Number:	**852627-0**
Report Date:	**12-Aug-2013**
Report Status:	**Final**
Supercedes :	**850237-0**

Certificate of Analysis

[redacted]

Method References	Testing Location
Dissolution (DISL:4)	**Covance Laboratories - Madison**

United States Pharmacopeia, Thirty Fourth Revision, <2040>, <711>, United States Pharmacopeial Convention, Inc.: Rockville, Maryland (2011).

Client Supplied Method

Testing Location(s)	Released on Behalf of Covance by
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Madison WI 53704
608-242-2712 x4170