
**Infant formula and adult
nutritionals — Determination of *trans*
and total (*cis* + *trans*) vitamin K₁
content — Normal phase HPLC**

*Formules infantiles et produits nutritionnels pour adultes —
Détermination de la teneur en vitamine K₁ trans et totale (cis +
trans) — Chromatographie liquide à haute performance (CLHP) en
phase normale*

(<https://standards.iteh.ai>)
Document Preview

ISO 21446:2019

<https://standards.iteh.ai/catalog/standards/iso/90381915-ade8-415b-ba70-06a3153f474e/iso-21446-2019>



iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

ISO 21446:2019

<https://standards.iteh.ai/catalog/standards/iso/90381915-ade8-415b-ba70-06a3153f474e/iso-21446-2019>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principle	1
5 Reagents and materials	2
6 Standard and solution preparation	2
6.1 Mixture with volume fraction of 10 % isopropanol in iso-octane	2
6.2 Mobile phase	2
6.3 Post-column electrolyte solution	3
6.4 Vitamin K ₁ (phytonadione) stock standard solution	3
6.4.1 Vitamin K ₁ (phytonadione) stock standard solution	3
6.4.2 Stock standard concentration (for non USP standard)	3
6.5 Vitamin K ₁ (phytonadione) intermediate I standard solution	3
6.6 Vitamin K ₁ (phytonadione) intermediate II standard solution	3
6.7 Vitamin K ₁ (phytonadione) working standard solutions	3
7 Apparatus	4
8 Procedure	4
8.1 Sample preparation	4
8.1.1 Liquid samples	4
8.1.2 Powder samples	5
8.1.3 Dry blended/non-homogenous powder samples	5
8.1.4 Wet blended powder samples	5
8.1.5 Extraction	5
8.2 HPLC analysis	6
8.2.1 Instrumental operating conditions	6
8.2.2 Instrument start-up	6
8.3 HPLC of standards and samples	7
8.4 Instrument shut-down	8
8.4.1 Short-term shut-down	8
8.4.2 Long-term shut-down	8
9 Calculations	8
10 Precision	10
10.1 General	10
10.2 Repeatability	10
10.3 Reproducibility	10
Annex A (informative) Example chromatograms	12
Annex B (informative) Precision data	14
Annex C (informative) Comparison between this document and EN 14148	18
Bibliography	20

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 34, *Food products* in collaboration with AOAC INTERNATIONAL. It is being published by ISO and separately by AOAC INTERNATIONAL. The method described in this document is equivalent to the AOAC Official Method 2015.09: *Trans vitamin K₁ in Infant, Pediatric, and Adult Nutritionals, HPLC with Fluorescence Detection*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.