

USP Pharmaceutical Ingredient Verification Program



MARK USAGE MANUAL



U.S. PHARMACOPEIA
The Standard of QualitySM



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SECTION 1—OVERVIEW

USP AND PHARMACEUTICAL INGREDIENT VERIFICATION

The United States Pharmacopeia's Pharmaceutical Ingredient Verification Program is intended to verify the quality of active pharmaceutical ingredients (API) and excipients supplied for use in the manufacture of drug products and other healthcare articles. USP subjects participating API and excipient manufacturers (referred to as participants in the remainder of this manual) to a GMP compliance audit, review of manufacturing and quality control documentation, and testing of selected lots of ingredient samples before determining if a participant's ingredients qualify to use the USP Verified Pharmaceutical Ingredient Mark on their ingredient labels, certificate of analysis, and communication materials.

Use of the USP Verified Pharmaceutical Ingredient Mark helps ingredient manufacturers assure their customers that the quality of the ingredients they are supplying has been rigorously tested and verified by an independent authority. When the mark appears on an ingredient container or carton, it represents that USP has evaluated the ingredient and found that:

1. The participant's quality system helps to ensure that the ingredient meets its label or certificate of analysis claims for identity, strength, purity, and quality.
2. The ingredient has been prepared under accepted good manufacturing practices (GMP) that ensure consistency in the quality of ingredients from batch to batch.
3. The ingredient meets its specifications' acceptance criteria.

This manual contains specific guidelines for use of the USP Verified Pharmaceutical Ingredient Mark on all ingredient container and carton labels and imprints, certificate of analysis, and other communication materials.

ABOUT USP

USP is a name doctors and pharmacists have trusted for nearly 200 years. As an independent, not-for-profit, scientific organization, USP works with manufacturers, setting the official standards for prescription and OTC medicines. USP's drug standards are enforceable by the FDA and also are recognized worldwide.

□ SECTION 2—

GENERAL POLICY ON USE OF THE USP VERIFIED PHARMACEUTICAL INGREDIENT MARK

2.1 Requirements to be met before using the mark

Before using the USP Verified Pharmaceutical Ingredient Mark, participants must

1. Receive written notification from USP that the ingredient for which they intend to use the mark meets program requirements.
2. Receive written notification from USP that the submitted artwork or proofs of container labels, imprints, or other materials on which the mark is to be used have been approved.

Please note that USP approval is required for text that refers to the mark as well as for the graphics and layout of all communication materials.

2.2 Materials on which the mark may be used

The USP Verified Pharmaceutical Ingredient Mark may be used on the following types of materials that relate to the approved ingredients for manufacturing purposes only:

1. Labels on industrial containers or cartons.
2. Imprints on industrial containers or cartons.
3. Certificate of Analysis.
4. Advertisements and promotional and sales collateral materials to be used in business-to-business marketing.
5. Exhibits and displays at trade shows.
6. Websites with proper information about the mark's meaning.

USP may approve use of the mark on any other materials on a case-by-case basis.

2.3 Intent and prohibited use of the mark

The USP Pharmaceutical Ingredient Verification Program is designed to elevate the standards of production and the purity of ingredients used in drug products. No statement of safety or efficacy is implied by the use of the USP Verified Pharmaceutical Ingredient Mark. USP disapproves of advertising or promotional material that implies safety or efficacy of products based on the product bearing the mark.

2.4 Avoidance of confusion with other USP Verified marks

USP also verifies dietary supplement products under its USP Dietary Supplement Verification Program and dietary supplement ingredients under its Dietary Supplement Ingredient Verification Program. Products and ingredients meeting the requirements of these Programs are awarded use of the distinctive USP Verified Dietary Supplement Mark or the USP Verified Dietary Supplement Ingredient Mark. The target audiences for these marks are dietary supplement consumers and manufacturers. USP wishes to keep these marks separate and distinct from the USP Verified Pharmaceutical Ingredient Mark, for which the target audience is drug product manufacturers.

2.5 Period of use

USP and the participant will agree upon a specific date when the approved ingredient bearing the USP Verified Pharmaceutical Ingredient Mark may be released into commerce. Thereafter, the participant may use the mark, in accordance with the requirements specified in this manual, for the term of the License Agreement between USP and the participant.

2.6 Re-evaluation or termination of use


USP reserves the right to require any verified ingredient, system, facility, or documentation to be retested or re-evaluated, or to stop use of the USP Verified Pharmaceutical Ingredient Mark if:

1. USP finds during its periodic post-verification evaluations that the mark is being misused, improperly used, or used in violation of the guidelines contained in this manual.
2. The ingredient no longer meets the criteria to carry the mark.
3. The ingredient is reformulated or the manufacturing process is changed and is determined to be a major change.

2.7 Clarity and good taste in use of the USP Verified Pharmaceutical Ingredient Mark

The following requirements apply to ingredient container and carton labels and any other materials referred to in Section 2.2 that feature the USP Verified Pharmaceutical Ingredient Mark.

1. The mark is the property of USP and may not be used without USP's explicit written approval. No attempt shall be made to recreate the mark or anything closely resembling it in any form.
2. Any use and language must be in good taste and not deceptive or misleading.

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3. Materials will not be approved by USP if they conflict with or appear to be in conflict with USP's policies and ethics, or if they are deemed offensive in any way, or contain attacks of a personal, racial, or religious nature.
 4. The mark shall be legible and shall not be used in any manner that detracts from its dignity.
 5. All claims of fact made for the approved ingredient, either stated or implied, must be accurate, consistent with program requirements, and meaningful in terms of the benefits offered.
 6. Care shall be taken not to state or imply that the mark indicates that USP endorses the safety or efficacy of the ingredient or that USP endorses the other goods and services of the ingredient's manufacturer.
 7. An approved ingredient shall not be advertised or displayed with unapproved ingredients in a manner that is confusing or misleading, or implies USP approval of the unapproved ingredients. In this regard, materials will be judged by the impression they create when viewed in their entirety.
 8. The mark shall not appear in conjunction with the seal or mark of any other group or organization or with any symbol likely to confuse people. The mark shall not be used in association with any of the participant's own trademarks in a manner that might suggest co-branding or otherwise create potential confusion as to the source of ownership of the mark.
 9. USP will not approve material that requires it to evaluate subjective proof. However, it may, at its discretion, allow neutral product comparisons. For example, "Compare with brand X" may be permitted, but not "Works better than brand X".

SECTION 3—

GUIDELINES FOR USE OF THE USP VERIFIED PHARMACEUTICAL INGREDIENT MARK

3.1 Size, elements, and appearance of the mark

The following guidelines apply to the use of the USP Verified Pharmaceutical Ingredient Mark on all materials listed in Section 2.2:

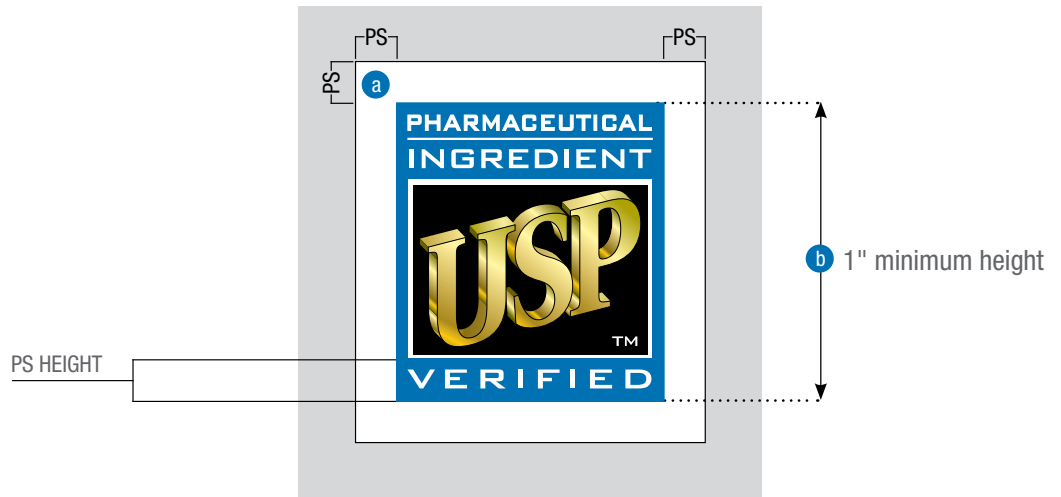
1. The mark consists of the text “PHARMACEUTICAL INGREDIENT VERIFIED”, the USP logo, and the accompanying graphics. The elements of the mark must not be separated. No elements, words, numbers, etc., shall be added to or removed from the mark.
2. After sending notification that an ingredient has been found to comply with the requirements of the program, USP will provide to the participant the electronic artwork for the USP Verified Pharmaceutical Ingredient Mark. The complete mark must always be reproduced from this electronic artwork, only resizing as required. A participant with requirements that cannot be met by reproducing the mark from the electronic artwork must contact USP for assistance (see Section 5).
3. Under no circumstances should the participant attempt to recreate the mark or any version thereof. Participants must not redesign, redraw, animate, rotate, or alter the proportions of the mark. They must not render it three-dimensional.
4. The mark must never be used without the ™ (trademark) symbol on the right side just below the USP logo (see example below).
5. On approved container and carton labels and imprints, the height of the mark should never be less than 2.5 inches (see example below). USP may, at its discretion, permit variations on review of the artwork or proofs.
6. On materials other than approved container and carton labels and imprints—such as certificate of analysis, advertising, promotions, and collateral—the height of the mark should never be less than 1 inch. USP may, at its discretion, permit variations on review of the artwork or proofs (see example below).



7. The mark, and any part thereof, must not be used as a decorative element, background, or pattern. Refer to Section 3.2 for additional dos and don'ts in the use of the mark.

SECTION 3—

GUIDELINES FOR USE OF THE USP VERIFIED PHARMACEUTICAL INGREDIENT MARK



Protected Space (PS) and Size

- a** **Protected space** should always be maintained around all sides of the USP Verified Pharmaceutical Ingredient Mark. See diagram above.
- b** **Minimum Size:** The **minimum** size for the reproduction of the USP Verified Pharmaceutical Ingredient Mark is 1" high.

Proper Logo Use

DO use the Mark only in the 4-color (CMYK) version provided by USP.

DO use the Mark so that all the text is clear and legible.

DO place the Mark vertically straight.

DO provide ample space around the Mark.



Proportions retained while resizing.

DO retain all elements of the Mark—text and graphics—in the right proportions while resizing.

On Colored Backgrounds

It's best to use the USP Verified Pharmaceutical Ingredient Mark on a clear white background. However, if the logo is to appear on a dark, complex, photographic, or patterned background, use the version of the Mark with the white surrounding rule to provide the necessary separation from the background.



Dark Background: Use Mark with white surrounding rule.



Complex Background: Use Mark with white surrounding rule.



Light Background: Use Mark without rule.



Tinted Background: Use Mark without rule.

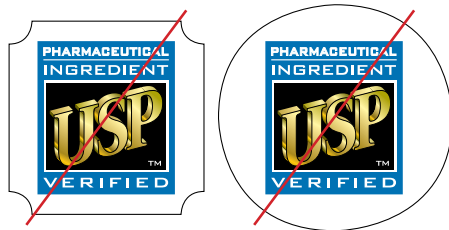
USP Verified Pharmaceutical Ingredient Mark Violations



DON'T use the Mark in colors or versions other than the ones provided by USP.



DON'T reverse the Mark.



DON'T place the Mark in a box or any other shape.



DON'T place any graphics or type inside the protected space.



DON'T alter the proportions when resizing the Mark.



DON'T tilt or rotate the Mark.



DON'T add a rule around the Mark or create additional colored boxes around the Mark.



DON'T add drop shadows, blends, filters, or effects.



DON'T place an image over the Mark.



DON'T isolate or displace elements of the Mark.

SECTION 4— PROCEDURES AND SCHEDULES FOR SUBMISSION AND REVIEW

4.1 What must be submitted

The participant must submit to USP artwork for the first print run of every kind and size of label or imprint on ingredient containers and cartons that include the USP Verified Pharmaceutical Ingredient Mark. New artwork must be submitted every time there is a change in the appearance, size, or positioning of the mark on the label or imprint.

For container or carton labels or imprints, a display of the way the mark will appear on the actual container/carton must accompany the artwork. The dimensions of the container or carton and the dimensions in which the mark will appear must be indicated on the artwork.

Where the mark is to be used in advertisements, exhibits, and promotional, collateral, or any other materials, artwork must be submitted to USP in each individual instance. Additionally, the stock or paper samples and bindery details must accompany the artwork for printed materials, where relevant.

For all materials, the artwork must be submitted in final mock-up form, in color, and, to the extent feasible, in the actual size in which it will be used. All text, graphics, and other elements must be in place. Artwork may be submitted electronically (via PDF files) or as hard copy. USP reserves the right to require review of actual production copies of any materials before use and distribution.

For all materials, including labels, in any language other than English, the participant must provide to USP a certified English translation along with materials in the original language.

4.2 Submission and approval process

Once USP sends the participant formal written notification that an ingredient submitted for verification is found to be in compliance with the requirements of the program, the participant must submit, for USP's review and approval, the artwork for the materials (as outlined in Section 2.2) where the mark is proposed to be used.

Within approximately ten calendar days of receiving materials for review, USP will provide the participant with written notification of approval or disapproval of the materials submitted, or if necessary, will request additional materials and information. While USP cannot guarantee adherence to a fixed schedule in all cases, every effort will be made to expedite review of materials submitted. The review may take longer if supporting data are not provided or are incomplete, or if USP requires additional information or materials to review.

If the materials submitted are not approved by USP because they are not in accordance with the mark usage guidelines provided in this manual, USP will provide written notification of its disapproval and give the participant an opportunity to correct or adjust deficiencies and resubmit the materials for approval. USP will work with the participant as needed to bring materials into compliance.

None of the materials submitted to USP review may be released for commercial use until USP returns the artwork for the materials to the participant stamped with “Approved for Use” and accompanied by a formal letter of approval.

□ SECTION 5— USP CONTACT INFORMATION

All labels and communication materials being submitted for USP’s review must be sent to:

Pharmaceutical Ingredient Verification Program
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: 301.816.8314 Fax: 301.816.8145
Email: PIVP@usp.org

Questions regarding use of the mark should be directed to:

Tia Morfessis
Director, Sales and Marketing Communications
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: 301.816.8284 Fax: 301.816.8263
Email: tcm@usp.org

Technical questions should be directed to:

V. Srinivasan, Ph.D.
Vice President, Verification Programs
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: 301.816.8334 Fax: 301.816.8145
Email: vs@usp.org





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