

MIL-X-37393
28 June 1976

MILITARY SPECIFICATION

XYLOMETAZOLINE HYDROCHLORIDE SOLUTION, N.F.

This specification is approved for use by all Departments and Agencies of the Department of Defense.

1. SCOPE

1.1 Scope: This specification covers Xylometazoline Hydrochloride Solution, N.F.

1.2 Classification. The solution covered by this specification shall be of the following sizes (See 6.2):

Size 1 - 1 pint

Size 2 - 15 ml

2. APPLICABLE DOCUMENTS

2.1 Issues of documents. The following documents, of the issue in effect on date of invitation for bids or request for proposals, form a part of this specification to the extent specified herein.

SPECIFICATIONS

FEDERAL

PPP-C-186 - Containers, Packaging and Packing for Drugs, Chemicals and Pharmaceuticals. (See 6.3)

STANDARDS

MILITARY

MIL-STD-105 - Sampling Procedures and Tables for Inspection by Attributes.

MIL-STD-129 - Marking for Shipment and Storage.

Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be of use in improving this document should be addressed to: Hq, Defense Personnel Support Center, ATTN: Directorate of Medical Materiel, DPSC-ATT, 2800 South 20th Street, Philadelphia, PA 19101, by using the self-addressed Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document, or by letter.

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(Copies of specifications and standards required by contractors in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

2.2 Other publications. The following documents form a part of this specification to the extent specified herein. Unless otherwise indicated, the issue in effect on date of invitation for bids or request for proposals shall apply.

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION

Federal Food, Drug, and Cosmetic Act and Regulations Promulgated
Thereunder.

(Application for copies should be addressed to the Food and Drug Administration, Washington, DC 20204.)

U. S. PHARMACOPEIAL CONVENTION, INC.

The United States Pharmacopeia.

(Application for copies should be addressed to the Mack Publishing Company, Easton, PA 18042.)

National Formulary.

(Application for copies should be addressed to the Mack Publishing Company, Easton, PA 18042.)

3. REQUIREMENTS

3.1 Material. Shall be Xylometazoline Hydrochloride Solution, 0.1 percent, and shall be in accordance with the tests, standards, and requirements of the N.F.

3.2 Ingredients.

3.2.1 Xylometazoline hydrochloride. The xylometazoline hydrochloride used in the manufacture of the solution shall comply with the tests, standards, and requirements of the N.F., solution including any supplements or revisions thereto.

3.2.2 Other ingredients. All other ingredients used in the manufacture of the solution shall be of U.S.P. or N.F. quality, or, if not included in either of these compendia, they shall be of a high quality and purity and suitable for use in the solution.

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3.3 Expiration dating period. The expiration dating period shall be not less than 36 months.

3.3.1 Delivery. Not more than 3 months of the expiration dating period shall have elapsed at the time of delivery to the Government.

3.4 Workmanship. The material and its containers shall be free from defects which detract from their appearance or may impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Supplier responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

4.1.1 Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and, (i) as to any expiration dated item, for the expiration dating period specified by the contractor for such item, or such longer period as may be required by regulation of any federal agency; or (ii) as to non-dated items, for not less than 3 years after delivery of the item to the Government.

4.1.2 No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

4.2 Lot. For purposes of this specification, a lot, batch, or control is that single, uniform, and homogeneous quantity of solution produced from one formulation, subjected to the same compounding and manufacturing operation, and filled into final containers.

4.3 Sampling. Sampling shall be conducted in accordance with MIL-STD-105.

TABLE I. Sampling.

For visual examination	Inspection level	AQL (percent defective)	Unit of product
Major	S-2	1.0	Filled immediate container
Minor	II	2.5	Filled immediate container

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4.3.1 Classification of defects. Examination will be conducted in accordance with the following classification of defects:

TABLE II. Classification of defects.

Categories	Defects <u>1/</u>
Major	
101	Solution not free from foreign matter.
102	Solution has crystal formation.
103	Solution not homogeneous.
Minor	
201	Exterior of immediate container is not free from contents or foreign matter.
202	Label not free from defacing marks and tears.

1/ Inspection is not restricted to the classified possible defects listed above.

4.4 Packaging inspection. The inspection of the intermediate package, packing and marking for shipment and storage shall be in accordance with quality assurance provisions of the applicable container specification and the marking requirements of MIL-STD-129.

4.5 Labeling inspection. Sampling shall be in accordance with MIL-STD-105 and the unit of product shall be the unit of issue. The inspection lot shall be the number of units of issue of each batch, lot, control number, etc., offered for inspection at one time. The inspection level for labeling shall be S-2 and the acceptance number shall be zero.

4.6 Tests. Tests shall be performed to determine compliance with all requirements of this document and all referenced documents.

5. PACKAGING

5.1 Packaging requirements. The requirements for packaging shall be in accordance with all applicable requirements of PPP-C-186 (See 6.3) and as specified herein.

5.2 Packaging. Packaging shall be level A or C as specified (See 6.1).

5.2.1 Unit of issue. One bottle containing 1 pint, size 1, or one bottle containing 15 ml, size 2, as specified, constitutes one unit of issue.

5.2.2 Level A.

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5.2.2.1 Immediate container: size 1 and size 2. The immediate container for size 1 and size 2 shall be a commercially available container considered acceptable by the Food and Drug Administration (FDA) for the product contained therein and shall be of such compatibility that neither the contents nor the container are altered in any way by each other.

5.2.2.2 Unit packaging. At the option of the contractor, each unit, size 1 or size 2, may be packaged as specified in 5.2.5 of PPP-C-186.

5.2.2.3 Intermediate packaging. Twelve (12) units of issue of size 1 shall be packaged as specified in 5.2.9 of PPP-C-186 or twelve units of issue of size 2 shall be packaged as specified in 5.2.7.1 of PPP-C-186.

5.2.3 Level C. Units shall be packaged in standard commercial containers of the size and kind commonly used, which will afford the degree of protection required for shipment and use of the product for its intended purpose.

5.3 Packing. Packing shall be level A, B or C as specified (see 6.1).

5.3.1 Level A. Twenty-four (24) units of issue of size 1 or four hundred thirty-two (432) units of issue of size 2 shall be packed as specified in 5.4.4 of PPP-C-186.

5.3.2 Level B. Twenty-four (24) units of issue of size 1 shall be packed as specified in 5.4.3.2 of PPP-C-186 or four hundred thirty-two (432) units of issue of size 2 shall be packed as specified in 5.4.3.1.1 of PPP-C-186.

5.3.3 Level C. The subject commodity shall be packed in substantial commercial containers of the type, size, and kind commonly used for the purpose, so constructed as to insure acceptance and safe delivery by common or other carriers, at the lowest rate, to point of delivery called for in the contract or purchase order.

5.4 Marking.

5.4.1 Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug and Cosmetic Act and shall include the information required below:

5.4.1.1 Immediate container. Each immediate container label shall bear the following information:

- (a) label information in accordance with commercial practice.
- (b) the expiration date.

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5.4.1.2 Unit package. Each unit package label shall bear the following information:

- (a) label information in accordance with commercial practice.
- (b) the National Stock Number.

- NOTES: (1) The National Stock Number shall not be preceded by any prefix.
- (2) Strip labeling may be used.
- (3) Label adhesion test shall not apply.
- (4) If a unit package is not supplied, the National Stock Number shall appear on the immediate container label.

5.4.2 Intermediate package. Each intermediate package shall be marked as specified in paragraph 5.5.3 of PPP-C-186. In addition, Type I shelf life marking as specified in MIL-STD-129 shall be shown. Marking shall include the legend:

"DO NOT PERMIT TO FREEZE."

5.4.3 Exterior container. Exterior containers shall be marked as specified in 5.5.4 of PPP-C-186. Type I Shelf life marking as specified in MIL-STD-129 shall also be shown. Marking shall include the legend:

"DO NOT PERMIT TO FREEZE."

6. NOTES

6.1 Ordering data. Procurement documents should specify the following:

- (a) Number and date of this specification.
- (b) National Stock Number.
- (c) Selection of applicable levels of packaging and packing (See 5.2 and 5.3).

6.2 This specification covers the following item(s):

<u>National Stock Number</u>	<u>Item Identification</u>	<u>Specification Designation</u>
6505-00-064-8672	XYLOMETAZOLINE HYDROCHLORIDE SOLUTION, NF, 0.1%, 1 pt (473 ml)	Size 1
6505-00-723-5020	XYLOMETAZOLINE HYDROCHLORIDE SOLUTION, NF, 0.1%, 15 ml	Size 2

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6.3 All references to PPP-C-186 refer to Interim Federal Specification PPP-C-00186B which is mandatory for use until superseded by a revision.

Custodians:

Army - MD

Navy - MS

Air Force - 03

Preparing activity:

Defense Supply Agency - DM

Project No. 6505-1533

