A-A-54470
15 August 1991

# COMMERCIAL ITEM DESCRIPTION

## NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE OTIC SUSPENSION, USP

The General Services Administration has authorized the use of this Commercial Item Description as a replacement for Military Specification MIL-N-37847 which is cancelled.

Salient Characteristics:

Shall be Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension, USP.

Shall be in accordance with the requirements of the USP.

Shall be a sterile otic suspension containing in each ml:

| | |
|---|---|
| Polymyxin B (as Polymyxin B Sulfates) | 10,000 units |
| Neomycin Sulfate | 5 mg (equivalent to 3.5 mg of Neomycin base) |
| Hydrocortisone | 10 mg (1 percent) |

The Otic Suspension should also include appropriate quantities of the following inactive ingredients: Cetyl Alcohol, Propylene Glycol, Polyssorbate 80, Water for Injection, and Thimerosol (preservative) 0.1%.

Workmanship. The suspension shall be free from defects which detract from its appearance or impair its serviceability.

Unit. Package (PG). Shall be supplied 10 ml in a commercially available bottle with separate sterilized calibrated dropper. One package containing one bottle and one dropper, as specified, constitutes one unit.

AMSC\NA FSC 6505

DISTRIBUTION STATEMENT A. Approved for public release; distribution is unlimited.

Contractor certification. The contractor shall certify that the product offered meets the salient characteristics of this description and conforms to the producers' own drawings, specifications, standards, and quality assurance practices. The Government reserves the right to require proof of such conformance prior to first delivery and thereafter as may be otherwise provided for under the provisions of the contract.

Regulatory requirements.

Federal Food, Drug and Cosmetic Act. If the product covered by this document has been determined by the U.S. Food and Drug Administration to be under its jurisdiction, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder. In addition, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of all other applicable Federal, State, and local statutes, ordinances, and regulations.

Recovered materials. The offeror/contractor is encouraged to use recovered material in accordance with Federal Acquisition Regulation Subpart 23.4 to the maximum extent practical.

Preservation, packaging, packing, labeling and marking. Unless otherwise specified, preservation, packaging, and packing shall be to a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc., involving shipment from the supply source to the receiving activity, plus reshipment from receiving activity, and shall conform to applicable carrier's rules and regulations. Intermediate and exterior package quantities and labeling and marking shall be as specified in the contract and/or order.

**NOTE:** The following National Stock Number is covered by this document:

| NSN | ITEM IDENTIFICATION |
|---|---|
| 6505-01-043-0230 | NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE OTIC SUSPENSION, USP, 10 ml |

Ordering data. Intermediate/exterior package quantities and labeling and marking must be specified in the contract and/or order.

MILITARY INTERESTS:

Custodians:

Army - MD
Navy - MS
Air Force - 03

PREPARING ACTIVITY:
DoD - MB

Agent:

DLA-DM

CIVIL AGENCY COORDINATING ACTIVITY:

VA-OSS
PHS
FDA-MPQAS

PGC 43347

Project No. 6505-5453