Pharmacologic Bronchoprovocation Agent for the Diagnosis of Bronchial Airway Hyperreactivity

Products administered to patients for diagnostic purposes are classified as Rx drugs by the FDA. Provocholine (methacholine chloride powder for inhalation) is the only FDA-approved methacholine chloride available for the diagnosis of bronchial airway hyperreactivity in humans.

As a prescription drug, Provocholine is subject to the FDA’s strict cGMP requirements for its manufacture and quality programs. Unlike USP grade chemicals, or laboratory reagents that are sometimes used to create challenge testing solutions, Rx Provocholine undergoes ten different analytical tests to ensure product purity and patient safety. As an inhalation drug, Provocholine is also subject to stringent microbiological testing for the control of microbes, molds, yeasts, and specific microbial strains that may compromise the human respiratory system upon administration.

Methacholine chloride and other respiratory drugs are sometimes compounded or mixed together from chemical ingredients that have not been approved by the FDA. Practitioners should be aware that there is no generic version of Provocholine and that it is the only FDA-approved methacholine chloride for use in humans.

Provocholine (methacholine chloride powder for inhalation) is indicated for the diagnosis of bronchial airway hyperresponsiveness in subjects suspected of having asthma.

WARNING: Provocholine (methacholine chloride powder for inhalation) is a bronchoconstrictor agent for diagnostic purposes only, and should not be used as a therapeutic agent. Provocholine inhalation challenge should be performed only under the supervision of a physician trained in and thoroughly familiar with all aspects of the technique of methacholine challenge, all contraindications, warnings and precautions, and the management of respiratory distress. Please consult the product package insert for more details.

To address the highly hygroscopic nature of the Methacholine Chloride drug product, Provocholine is manufactured in a highly controlled environment, including operation under nitrogen.

Moreover, packaging in airtight vials ensures the quality and potency of the drug. The latter is critical in the diagnostic process, since methacholine challenge testing is dependent on a dose response, whereby the accuracy of the dose is critical in avoiding diagnostic errors.

Quality assurance with Provocholine does not end at manufacturing. As with all FDA approved Rx drugs, samples are retained and routinely tested to ensure the quality of all product in the supply chain. Additionally, Methapharm has staff on hand to respond to any questions that your facility may have with respect to Provocholine or bronchoprovocation challenge testing.

Finally, as a prescription drug for human use, methacholine chloride is subject to pedigree requirements. Methapharm fully complies with all applicable state Rx drug pedigree requirements for Provocholine.

Methapharm provides training materials, resources, equipment, and supplies, as well as customized methacholine challenge testing kits for your facility.

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THE 7 Ps OF PROVOCHOLINE:
WHY PROVOCHOLINE IS THE AGENT OF CHOICE FOR BRONCHOPROVOCATION CHALLENGE TESTING

✓ Purity – Chemical
Provocholine (methacholine chloride) is an FDA approved Rx drug and, as such, is subject to the FDA’s stringent regulations on drug purity. Many laboratory reagents (e.g. USP grade) are tested for chemical assay (a simple measure of the potency of a substance). To ensure Rx drug product safety, Provocholine is tested for product purity by setting very strict limits for all potential impurities - the product is subject to ten different analytical tests to certify product quality using sophisticated analytical equipment.

✓ Purity – Biological
Quality programs for FDA-approved Provocholine comprise microbiological testing which include product testing for total aerobic microbial count, molds and yeasts. Provocholine is also tested to ensure the complete absence of Staphylococcus aureus, Escherichia coli, Salmonella sp. and pseudomonas aeruginosa.

✓ Precision
Provocholine is precision weighed to ensure the accuracy of the 100 mg dose. As the methacholine challenge test is a dose response test, accuracy of the dose is essential.

✓ Pedigree
Provocholine is the only FDA-approved methacholine chloride for human use. Each vial is labeled with the product NDC, the lot number, and an expiry date. Further, Methapharm complies with state Rx drug pedigree laws.

✓ Process
As an FDA approved drug, Provocholine is manufactured under strict cGMP conditions in inspected facilities. It is manufactured in a highly controlled environment including operation under nitrogen to address the highly hygroscopic nature of the drug product.

✓ Packaging
Provocholine is packaged in airtight vials to ensure that the quality and potency of the drug is not compromised by exposure to air. A green flip-off seal with grey stopper guarantees ease of use.

✓ People
Methapharm’s Customer Service Support Team includes a Licensed Respiratory Therapist to support product inquiries. We also provide assistance with IRB approvals, access to a Medical Advisor, systemic adverse reaction tracking procedures and Regulatory Specialists.

Provocholine (methacholine powder for inhalation) is indicated for the diagnosis of bronchial airway hyperresponsiveness in subjects suspected of having asthma. The methacholine challenge test with Provocholine provides a measure of the severity of asthma. The methacholine challenge test with Provocholine may be used to confirm occupational asthma.

METHAPHARM - YOUR SINGLE SOURCE FOR YOUR BRONCHOPROVOCATION TESTING SUPPLIES

ASTHMA DIAGNOSIS STUDIES
SPUTUM STUDIES
INCLUSION/EXCLUSION CRITERIA
ALLERGY STUDIES
IMMUNOLOGICAL STUDIES
EPIDEMIOLOGICAL STUDIES

CUSTOM RESEARCH KITS/CLINICAL SUPPLY MANAGEMENT

Custom research kits from Methapharm conveniently include everything required to complete a Methacholine Challenge Test or other diagnostic tests. Our custom kits can be designed to meet the needs of your facility’s protocol for a variety of study types.

www.provocholine.com

Methapharm carries a full complement of devices such as Dosimeters, Sputum Induction Devices, and Nebulizers, along with related accessories and replacement parts.

www.methapharm.com • sales@methapharm.com

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