

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22368Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

28 September 2009

NDA: 22-368/N-000

Drug Product Name

Proprietary:

Aridol.

Non-proprietary:

Mannitol bronchial challenge test.

Review Number: 1.

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
27 FEB 2009	27 FEB 2009	18 JUN 2009	18 JUN 2009

Applicant/Sponsor

Name:

Pharmaxis, Ltd.

Address:

Unit 2, 10 Rodborough Rd
Frenchs Forest NSW 2076
Australia

Representative:

Valerie Waltman

Telephone:

610-363-5120 ext. 103

Name of Reviewer:

John W. Metcalfe, Ph.D.

Conclusion:

Recommend approval.

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original NDA.
 - 2. SUBMISSION PROVIDES FOR:** A new drug product.
 - 3. MANUFACTURING SITE:**
Pharmaxis Ltd.
Unit 2, 10 Rodborough Rd,
Frenchs Forest NSW 2086
Australia
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Dry powder capsule.
 - Oral inhalation.
 - 0, 5, 10, 20 and 40 mg.
 - 5. METHOD(S) OF STERILIZATION:** The product is (b) (4)
 - 6. PHARMACOLOGICAL CATEGORY:** The subject drug product is indicated for the assessment of bronchial hyper-responsiveness to aid in the diagnosis of patients ≥ 6 years of age with symptoms of or suggestive of asthma.
- B. SUPPORTING/RELATED DOCUMENTS:** None.
- C. REMARKS:**
The NDA is submitted electronically in the CTD format.

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – NDA 22-368/N-000 is recommended for approval on the basis of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – Not applicable.

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** –  (b) (4)
- B. Brief Description of Microbiology Deficiencies** – There are no microbiology deficiencies identified.
- C. Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

III. Administrative

- A. Reviewer's Signature** _____
John W. Metcalfe, Ph.D.
- B. Endorsement Block** _____
Stephen Langille, Ph.D.
- C. CC Block**
N/A

6 pages has been withheld in full as B(4) CCI/TS immediately following this page

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22368	ORIG-1	PHARMAXIS LTD	ARIDOL POWDER FOR INHALATION

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOHN W METCALFE
10/02/2009

STEPHEN E LANGILLE
10/07/2009