



Phytex Australia

Leading global phytochemist manufacturers

Phytex is an Australian owned and operated company specialising in the extraction, isolation and purification of active pharmaceutical ingredients (APIs) derived from Australian native flora. Founded in 1979 and headquartered in Sydney Australia, Phytex is a leading supplier to major global pharmaceutical manufacturers and research organisations.

Zero product
recalls since
1979



Experts in extraction,
isolation and purification
from natural sources



Australian
owned, operated
and sourced



Guaranteed consistent quality, supply and delivery

Phytex reliability and project technical solutions enable our customers to focus on critical and technical challenges in the product formulation, application, clinical trials and expansion processes.

Security of supply is underpinned by **strong supplier partnerships**. Phytex has maintained relationships with key raw material suppliers for more than 25 years, for the shared benefit of customers, manufacturers and Australian farmers.

With a highly flexible operational capacity, Phytex specialises in supporting **early-stage drug product development** requirements with the ability to **scale production to commercial quantities** (kilograms to tonnes) and meet the expectations of global market operators.

An experienced and trusted partner

Phytex has a long history of partnering and supplying APIs to global pharmaceutical clients to support their research, development and formulation for both clinical trials and commercial needs.

Phytex also has the onsite expertise and capacity for:

- **contract manufacturing** for the pharmaceutical, food and research industries
- **outsourcing stages of development**, such as the extraction and isolation manufacturing processes
- **research and development, regulatory navigation and commercial scaling consultation** for the entire drug development journey



Exploration

Pre-development

NDA/ ANDA
Support



Supply

Quality

Stability
Security



Manufacture

Finished APIs

Contract
manufacturing



Support

Technical

Commercial

Our API products

USDMF
7415

Scopolamine (Hyoscine) Hydrobromide
USP & EP specification
Active (1988) Type II USDMF & CEP (2023)
Active Type I MF (Health Canada)

USDMF

Atropine Base
USP and EP specification
Type II USDMF*

USDMF
7408

Scopolamine Base
EP specification
Active (1988) Type II USDMF

USDMF

Atropine Sulfate
USP specification
Type II USDMF*

USDMF
10880

Castanospermine
USP specification
Active (1988) Type II USDMF

USDMF
7410

Methscopolamine Bromide
USP specification
Active (1988) Type II USDMF

*DMF in development

Our intermediates & KSM

Available
now

Scopine HCl
Specification upon request
Tiotropium Br Intermediate

Available
now

Scopolamine HBr
CP & USP specification
Intermediate grade

Our API pipeline

Evaluation
ongoing

Cochicine Base
USP, EP & CP specification

Evaluation
ongoing

Solasodine Base
Specification upon request

Exceptional track record at global standards

With **40 years of experience** in Good Manufacturing Practice, Phytex maintains an exceptional track record of compliance recognised by all international regulators of the markets we work in. These include the Australian Therapeutic Goods Administration (**TGA**), United States Food and Drug Administration (**USFDA**), Health Canada (**UC**), European Directorate Quality for the Quality of Medicines (**EDQM**) and Medicines and Healthcare products Regulatory Association (**MHRA**).

Our expertise lies in alkaloids and glycosides used in pharmaceutical marketed prescription medicines, medical research and product development; all manufactured to United States (USP) and European Pharmacopeia (EP) specifications.

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