Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Intenza International Pty Ltd

for approval to supply

Ignite

ARTG Identifier AUST L 125617

ARTG Start date 16/02/2006

Product type Listed Medicine

Manufacturer Details	Address	Manufacturing Steps
Alaron Products Ltd	13 Bolt Road Tahunanui, Nelson, New Zealand	Manufacture of dosage form Release for supply Packaging and labelling
Amdel Limited T/As Bureau Veritas Pharmaceutical	Units 1 & 16 & 17 & 18 / 8 Leighton Place ASQUITH, NSW, 2077 Australia	Testing chemical and physical
Analytica Laboratories Pty Ltd	26 Roseberry Street BALGOWLAH, NSW, 2093 Australia	Testing chemical and physical
GMP Pharmaceuticals Pty Limited	7-9 Amax Avenue GIRRAWEEN, NSW, 2145 Australia	Manufacture of dosage form Release for supply Packaging and labelling
Primary Industries Management Services Pty Ltd T/A ConMac Laboratory Services	6 Glasson Drive BETHANIA, QLD, 4205 Australia	Testing microbial Testing chemical and physical

ARTG Standard Conditions

The above Medicine Listed has been entered on the Register subject to the following conditions:

- Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.
- The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.
- The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.
- The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.
- All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.
- The sponsor shall not supply the listed medicine after the expiry date of the goods.
- Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the

sponsor.

Products Covered by This Entry

1. Ignite

Product Specific Conditions

· No specific conditions have been recorded against this entry.

Product Permitted Indications

No permitted indications have been recorded against this entry.

Product Indication Requirements

No indication requirements have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

· Used in Chinese, Indian and European traditional medicine to increase libido and stamina

Warnings

No warnings have been recorded against this entry.

Dosage Form

Capsule, hard

Route of Administration

· Oral

Visual Identification

Not recorded

Additional Product information

Product Formulation(s)

Active Ingredients

	Quantity	Units
Tribulus terrestris	190	mg
Epimedium brevicornu	70	mg
Avena sativa	125	mg