



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Natures Help Pty Ltd ATF Natures Help Trust**

for approval to supply

## Organic Turmeric with Black Pepper and Ginger Capsules

ARTG Identifier AUST L 283512

ARTG Start date 13/12/2016

Product type Listed Medicine

Manufacturer Details	Address	Manufacturing Steps
BJP Laboratories Pty Ltd	2 Alloy Street Yatala, QLD, 4207 Australia	Manufacture of dosage form Packaging and labelling Release for supply Secondary packaging
BJP Laboratories Pty Ltd	1 Alloy Street Yatala, QLD, 4207 Australia	Testing chemical and physical Testing microbial
BJP Laboratories Pty Ltd	Unit 2 / 38 Computer Road YATALA, QLD, 4207 Australia	Secondary packaging Release for supply Packaging and labelling Manufacture of dosage form
Gold Coast Laboratories Pty Ltd	52 Junction Road BURLEIGH BC, QLD, 4220 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 chemical and physical Testing microbial
Southern Cross Plant Science Analytical Services	Level 3 T Block and N Block Military Road Southern Cross University LISMORE, NSW, 2480 Australia	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. Organic Turmeric with Black Pepper and Ginger Capsules

#### Product Specific Conditions

No specific conditions have been recorded against this entry.

#### Product Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support general health and wellbeing
- Traditionally used in Asian medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Asian medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Asian medicine to helps enhance/promote healthy digestive system function
- Traditionally used in Asian medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Asian medicine to relieve digestive discomfort
- Traditionally used in Asian medicine to decrease/reduce/relieve digestive spasms
- Traditionally used in Asian medicine to hepatoprotectant/protect the liver
- Traditionally used in Asian medicine to promote bile flow from liver/chloretic
- Traditionally used in Asian medicine to maintain/support healthy liver function

#### Product Indication Requirements

- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

#### Product Standard Indications

No standard indications have been recorded against this entry.

#### Product Specific Indications

No specific indications have been recorded against this entry.

#### Warnings

- If symptoms persist consult your healthcare practitioner (or words to that effect). ( S )

#### Dosage Form

Capsule, hard

#### Route of Administration

- Oral

#### Visual Identification

Not recorded

#### Additional Product information

#### Product Formulation(s)

##### Active Ingredients

	Quantity	Units
Ginger Powder	50	mg
Piper nigrum	5	mg
Curcuma longa	680	mg

