Government of South Australia
SA Health

CONTROLLED SUBSTANCES ACT, 1984

146850

Licence Number: 2018-82713

MANUFACTURER'S LICENCE

GD PHARMA PTY LTD
46 - 46A BEULAH RD
NORWOOD SA 5067

is hereby licensed, in accordance with section 31(1)(ag) of the *Controlled Substances Act 1984* (hereafter referred to as 'the Act') to manufacture, produce, pack and sell or supply the following poisons:

SCHEDULE 8 DRUGS

at the following location(s):

46A BEULAH RD, NORWOOD SA 5067

Subject to requirements under the Act, the Controlled Substances (Poisons) Regulations 2011, and the following conditions:

1. The premises listed above must have a monitored alarm system.
2. Wholesaling of therapeutic drugs must comply with the 'Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8'.
3. The therapeutic drugs must be stored under conditions that ensure the stability and efficacy of the products. The drugs must be packed in such a manner that they do not leak during transport. They must not be transported with food or any component of food for human or animal consumption unless effectively separated from the food or food component to avoid possible contamination.
4. The licensee shall comply with the requirements of the SA Health "Suspected Theft or Loss of Drugs or Substances from Licence or Permit Holders" policy dated September 2011.
5. An accurate record of the manufacture and sale of the therapeutic drugs is to be kept.
6. A report showing details of drug movements is to be made to Commonwealth Department of Health at weekly intervals.
7. The persons approved to be responsible for the manufacture, storage, ordering, record keeping and sale of these drugs are:

   MR ANTONY CONDINA

THIS LICENCE WILL EXPIRE ON 21/07/2021

Dated at Adelaide this 22/07/2018

delegate of the Minister, Controlled Substances Act.

AMOUNT PAID: $1,149.00
RECEIPT No.: 0000017855

Lachlan Hutchison

CONTROLLED SUBSTANCES ACT, 1984

8. Access to such drugs and the drug register is to be restricted to the approved responsible persons and:

—

9. The drugs are to be stored and transported in accordance with the "Code of Practice for the Storage and Transport of Drugs of Dependence".

10. The sale or supply of such drugs shall be only to a person authorised or licensed to have possession of such drugs.

11. A register shall be kept as required by Regulations 39, 40 and 41 of the Controlled Substances (Poisons) Regulations 2011.

delegate of the Minister, Controlled Substances Act.

Lachlan Hutchison

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2012-LI-00154-3

Granted to:

GD Pharma Pty Ltd
ABN: 49 611 947 712

Manufacturing Site Address:

46a Beulah Road
NORWOOD SA 5067

The manufacturer above is hereby authorised under section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile	Eye Drops	Therapeutic Goods for Clinical Trials	Sterile Finished Product Manufacture - excluding Testing
Medicine manufacture	Sterile	Injections	Therapeutic Goods for Clinical Trials	Sterile Finished Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Oral Liquid, solution	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Sterile	Eye Drops	Registered Therapeutic Good	Sterile Finished Product Manufacture - excluding Testing
Medicine manufacture	Sterile	Injections	Registered Therapeutic Good	Sterile Finished Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Nasal Drops	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Nasal Drops	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full Product Manufacture - excluding Testing

This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
This Licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.
The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2012-LI-00154-3

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and regulations 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under section 40(1) or 40(2) of the *Therapeutic Goods Act 1989*.

Originally Granted: **19 March 2013** Date Revised: **6 March 2018**

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TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-2012-LI-00154-3

Issued to:

GD Pharma Pty Ltd
ABN: 49 611 947 712

Manufacturing Site Address:

46a Beulah Road
NORWOOD SA 5067

In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under section 40(4) of the *Therapeutic Goods Act 1989* and regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

Sterile products are limited to terminally sterilised products only.

Quality Control testing is excluded from this licence.

The licence is limited to the manufacture of liquid dosage forms including nasal sprays. The licence excludes the manufacture of Penicillins and Cytotoxic drugs.

Persons currently nominated under section 37(1)(e) of the Act as having control:

Production: Andrew Gia-Phong Vuong

Quality Control: Maria Fernanda Bolivar

Originally imposed: **19 March 2013** Date Revised: **6 March 2018**

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TGA Health Safety Regulation

RIBOLEX™

CORNEAL CROSS-LINKING RIBOLFAVIN SOLUTION

PRESCRIBING INFORMATION

- **RIBOLEX™ Isotonic:** Riboflavin 5' (Vitamin B2) Phosphate (0.1%) with 20% Dextran 500
- **RIBOLEX™ Hypotonic:** Riboflavin-5' (Vitamin B2) Phosphate (0.1%) Solution
- **RIBOLEX™ Rapid:** Riboflavin-5' (Vitamin B2) Phosphate (0.1%) with 1.1% HPMC, Saline
  - For topical ophthalmic application only.
  - For use in conjunction with corneal cross-linking device for treatment of progressive keratoconus.
  - Available in Australia under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) Category-C: https://www.tga.gov.au/sites/default/files/special-access-scheme-category-c-form.pdf

INDICATION FOR SINGLE USE:

- When used in association with ophthalmic UV-A irradiation by Cross-Linking device. Riboflavin 5'-phosphate sodium (Vitamin B2) is the precursor of two coenzymes, flavin adenine dinucleotide and flavin mononucleotide, which catalyze oxidation /reduction reactions involved in a number of metabolic pathways.
- Under the conditions used for corneal collagen cross-linking, riboflavin 5'- phosphate functions as a photoenhancer and generates singlet oxygen which is responsible for the cross-linking as well acts as a filter protecting leakage of harmful UV rays to the inner retina.

DOSAGE FORMS & SRENGHTS:

- **Isotonic Solution** suppled in a sterile 3ml glass syringe containing 1.46mg/ml riboflavin 5'-phosphate in 20% Dextran 500 ophthalmic solution. (Approx. 40 application drops per unit).
- **Hypotonic Solution** supplied in a sterile 1ml glass syringe containing \ 1.46mg/ml riboflavin 5'-phosphate ophthalmic solution.(Approx. 12 application drops per unit).
- **Rapid Solution** supplied in a sterile 2ml glass syringe containing \ 1.46mg/ml riboflavin 5'-phosphate ophthalmic solution.(Approx. 24 application drops per unit).

COMPOSITION

Active Ingredients:

- Riboflavin 5-Phosphate

Inactive Ingredients:

- Dextran 500 (Isotonic solution only)
- HPMC (Rapid solution only)
- Sodium chloride
- Sodium phosphate
- Sterile water for injectable solution

CONTRAINDICATIONS

Ribolex™ ophthalmic solution has no known contraindications.

Avoid use in cases of hypersensitivity reactions to the components of the product or to other chemically related substances. **Ribolex™** is not recommended in the following:

- Pregnancy.
- In conjunction with any eye medication.
- Treatment of pediatric patients below the age of 14.

SIDE EFFECTS, ADVERSE REACTIONS

- No systemic side effects regarding the ocular surface have been reported from Ribolex™ compound.
- The most common ocular adverse reactions in CXL-treated eye were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision.

CAUTIONS

- **Ribolex™ must** be kept away from direct light.
- **Ribolex™** should be ideally stored at a temperature between +4° and +12°C (if not refrigerated or in transport the temperature should not exceed +24°C).
- Do not touch the eye surface or other objects with the syringe tip in order to avoid the risk of contamination.
- **Ribolex™** must not be used after one hour from initial use
- The syringe must not be reused for more than one patient.
- **Ribolex™** must not be utilized after the expiry date indicated on the package.
- **Ribolex™** must not be used if package appears damaged.

DOSAGE AND ADMINISTRATION

- **Ribolex™ Isotonic** is applied on corneas with thickness of 400 microns or above.
- **Ribolex™ Rapid** is s formulated with no dextran thus reducing corneal thinning. It has a diffusion rate of twice that of standard isotonic riboflavin. Allows faster soaking time and higher power irradiation.
- **Ribolex™ Hypotonic** to be applied on corneas less than 400 microns thick until minimum thickness achieved. The Hypotonic solution can be used to induce transient corneal oedema with thickening of the corneal stroma before UV-A irradiation is applied to avoid endothelial cell damage.

Corneal Soaking (Stage 1):

- Debride the epithelium using standard aseptic technique using topical anesthesia.
- Subsequently apply 1 drop of Ribolex Isotonic topically on the eye every 2 minutes for 30 minutes.
- After 30 minutes, examine the eye under slit lamp for presence of a yellow flare in the anterior chamber.
- If flare is not detected, apply 1 drop of Ribolex Isotonic every 2 minutes for an additional 2 to 3 drops and recheck for yellow flare. Repeat as necessary.
- Once flare is observed, perform ultrasound pachymetry. If corneal thickness is less than 400 microns, apply 2 drops of Hypotonic every 5 to 10 seconds until the corneal thickness increases to at least 400 microns.

UV Irradiation (UV Cross-Linking Stage 2):

- Ribolex™ Riboflavin is suitable for corneal cross-linking in conjunction with all FDA and or CE certified CXL device types.
- The CXL device user must familiarise themselves with the specific device instructions and user settings.
- UV Irradiation should not be performed unless this 400-micron threshold is met and the yellow flare is seen.
- Irradiate the eye for 30 minutes at 3mW/cm2 during irradiation; continue topical instillation of Ribolex ™ Isotonic onto the eye every 2 minutes for the 30-minute irradiation period.

NOTE: Operating physician must be fully trained and familiarize themselves with the relevant CXL device Operator's Manual for the specific Device instructions.

PATIENT COUNCELING INFORMATION

- Patients should be advised not to rub their eyes for the first five days after their procedure.
- Patients may be sensitive to light and have a foreign body sensation.
- Patients should be advised that there may be discomfort in the treated eye and that sunglasses may help with light sensitivity.
- If patients experience severe pain in the eye or any sudden decrease in their vision, they should be advised to contact their physician immediately.
- If the bandage contact lens that was placed on the patient's eye on the day of treatment falls out or becomes dislodged, the patient should be advised not to replace it and to contact their physician immediately.
- Treated patient should be instructed to NOT drive vehicles or operate any kind of machinery after cross-linking procedure, until their visual acuity is restored.

MISCELLANEOUS

Ribolex™ is supplied in single sterile syringe sealed in a single pouch and supplied in a bulk pack of five (5) single-use units per box.

Expiration Date.

Do Not Reuse / Single Use.

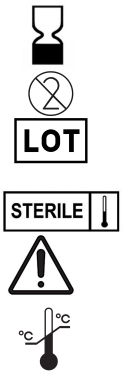
LOT= Production Batch.

Sterile by Autoclave 121°C, 15min.

Store away from sunlight.

Follow instructions for use supplied.

For prolonged Recommended to store around 4-8°C.



MANUFACTURED BY:

GD PHARMA PTY LTD

46 Beulah Rd, Norwood SA 5067
Adelaide, Australia

T: +61 8 8362 3927
E: info@gdpharma.com
W: www.gdpharma.com

UNLESS OTHERWISE SPECIFIED JOBS ARE QUOTED TO INCLUDE 1 X ALTERATION TO PROOFED ARTWORK, ANY EXTRA CHANGES MAY INCUR EXTRA COSTS

CustomCartons
Member of the Detmold Group

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PLEASE TICK A BOX

APPROVED AS IS ☐ NAME _____ SIGN _____ DATE _____

APPROVED WITH ALTERATIONS ☐

NEW PROOF REQUIRED ☐

Office Use

Organisation: GD Pharma Description: Ribolex Carton Proof No.: 4

Size: 99 x 50 x 145* Date: 16.11.18 Inventory: GDPH006 Drawing No.: 31247A

*Size may vary +/-1mm for Solid Board & +/- 3mm for Litho Laminated cartons unless specified & agreed upon by both parties in writing

IN ORDER FOR US TO GUARANTEE QUALITY, THIS PROOF MUST BE SIGNED AND RETURNED BEFORE WORK CAN PROCEED

Colours as specified by client order

PMS 3385	Deep Blue	AQ Gloss Varnish					

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CSF290

SAFETY DATA SHEET

Version 3.7

Revision Date 05.07.2013

Print Date 09.06.2014

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product name : (−)-Riboflavin

Product Number :
Brand :

1.2 Other means of identification

Lactoflavin
Vitamin G
Vitamin B2

1.3 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.4 Details of the supplier of the safety data sheet

Company : The Green Dispensary Compounding Pharmacy

Telephone :
Fax :

1.5 Emergency telephone number

Emergency Phone # :

2. HAZARDS IDENTIFICATION

2.1 GHS Classification

Not a dangerous substance according to GHS.

2.2 GHS Label elements, including precautionary statements

Pictogram none

Signal word none

Hazard statement(s) none

Precautionary statement(s) none

Not a dangerous substance according to GHS.

2.3 Other hazards - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms : Lactoflavin

Vitamin G
Vitamin B2

Formula	:	$C_{17}H_{20}N_4O_6$
Molecular Weight	:	376.36 g/mol
CAS-No.	:	83-88-5
EC-No.	:	201-507-1

none
No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1 Description of first aid measures

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact
Wash off with soap and plenty of water.

In case of eye contact
Flush eyes with water as a precaution.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
no data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
Carbon oxides, nitrogen oxides (NOx)

5.3 Advice for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information
no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Avoid dust formation. Avoid breathing vapours, mist or gas.
For personal protection see section 8.

6.2 Environmental precautions
Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up
Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections
For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed.Normal measures for preventive fire protection.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

A part from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits
We are not aware of any national exposure limit.

8.2 Exposure controls

Appropriate engineering controls
General industrial hygiene practice.

Personal protective equipment

Eye/face protection
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374
If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection
Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection
Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: Eye drop Colour: dark yellow
b)	Odour	no data available
c)	Odour Threshold	no data available
d)	pH	7.0
e)	Melting point/freezing point	Melting point/range: 290 °C
f)	Initial boiling point and boiling range	no data available
g)	Flash point	no data available
h)	Evapouration rate	no data available
i)	Flammability (solid, gas)	no data available
j)	Upper/lower flammability or explosive limits	no data available
k)	Vapour pressure	no data available
l)	Vapour density	no data available
m)	Relative density	no data available
n)	Water solubility	no data available
o)	Partition coefficient: n-octanol/water	no data available
p)	Auto-ignition temperature	no data available
q)	Decomposition temperature	no data available
r)	Viscosity	no data available
s)	Explosive properties	no data available
t)	Oxidizing properties	no data available

9.2 Other safety information
no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity
no data available

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
no data available

10.4 Conditions to avoid
no data available

10.5 Incompatible materials
Strong oxidizing agents, Reducing agents, Bases, Calcium, Metallic salts

10.6 Hazardous decomposition products
Other decomposition products - no data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - rat - > 10,000 mg/kg

Skin corrosion/irritation
no

Serious eye damage/eye irritation
no

Respiratory or skin sensitisation
no

Germ cell mutagenicity
no data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
no data available

Specific target organ toxicity - single exposure
no

Specific target organ toxicity - repeated exposure
no

Aspiration hazard
no data available

Additional Information
RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
no

12.2 Persistence and degradability
no data available

12.3 Bioaccumulative potential
no data available

12.4 Mobility in soil
no data available

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

no data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1 UN number
ADR/RID: - IMDG: - IATA-DGR: -

14.2 UN proper shipping name
ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA-DGR: Not dangerous goods

14.3 Transport hazard class(es)
ADR/RID: - IMDG: - IATA-DGR: -

14.4 Packaging group
ADR/RID: - IMDG: - IATA-DGR: -

14.5 Environmental hazards
ADR/RID: no IMDG Marine pollutant: no IATA-DGR: no

14.6 Special precautions for user
no data available

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons
no data available

Carcinogen classification under WHS Regulation 2011, Schedule 10
Not listed

Notification status

AICS:	On the inventory, or in compliance with the inventory
DSL:	All components of this product are on the Canadian DSL.
ENCS:	On the inventory, or in compliance with the inventory
IECSC:	On the inventory, or in compliance with the inventory
ISHL:	Not in compliance with the inventory - Riboflavin
KECI:	On the inventory, or in compliance with the inventory
NZIoC:	Not in compliance with the inventory - Riboflavin