

ORIGINAL APPROVAL NO. IMPY2000088

Health Sciences Authority Republic of Singapore

THE HEALTH PRODUCTS ACT (CHAPTER 122D) THERAPEUTIC PRODUCTS REGULATIONS 2016

APPROVAL TO IMPORT THERAPEUTIC PRODUCTS CONTAINING **PSYCHOTROPIC SUBSTANCES**

Distribution:

Duplicate (Copy 2) - To Competent Authority of Exporting Country

Original - To Importer

Duplicate (Copy 3) - To Health Products Regulation Group, Health Sciences Authority,

Duplicate (Copy 1) - To Exporter

Republic of Singapore

Name and Address of Importer	Name and Address of Exporter
GOVIN HOLDINGS PTE LTD 21 BUKIT BATOK CRESCENT #05-74 WCEGA TOWER SINGAPORE 658065	GLAND PHARMA LIMITED SURVEY NO.143 TO 148, 150, 151 NEAR GANDIMAISAMMA X ROAD DUNDIGAL POST, MEDCHAL-MALKAJGIRI HYDERABAD 500043 TELANGANA INDIA
James and Occasible of Culatones as Deconstation, and if a	oplicable, Pharmaceutical Dosage Form and Strengths, to be
	phicable, Friamaceutical bosage from and Strengths, to be
mported: MIDAZOLAM INJECTION 2mg/2ml, Each 2 ml vial conta	
mported: MIDAZOLAM INJECTION 2mg/2ml, Each 2 ml vial conta	
imported: MIDAZOLAM INJECTION 2mg/2ml, Each 2 ml vial conta Quantity: 460000 vials	
manne and Quantity of Substance of Preparation, and if a imported: MIDAZOLAM INJECTION 2mg/2ml. Each 2 ml vial conta Quantity: 460000 vials Total Base Psychotropic Substance Content: Total Midazolam Base = 920 gram(g)	
mported: MIDAZOLAM INJECTION 2mg/2ml. Each 2 ml vial conta Quantity: 460000 vials Total Base Psychotropic Substance Content:	
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mported: MIDAZOLAM INJECTION 2mg/2ml, Each 2 ml vial conta Quantity: 460000 vials Total Base Psychotropic Substance Content: Total Midazolam Base = 920 gram(g)	ins 2 mg of Midazolam base.

The above-mentioned Importer is hereby licenced to import the substance(s) specified in the Approval from the Exporter named. This Approval is issued subject to the Conditions stipulated in this Approval.

This Approval takes effect from 03 June 2020 and, unless revoked, shall expire on 02 December 2020.

Date of Issue Fee

: 03 June 2020

Application Number : 2062373K

: \$ 103

All persons issued with an Approval to Import Therapeutic Products Containing Psychotropic Substances under the Health Products Act (HPA) must comply with the HPA and their regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Licensees must also comply with all other applicable laws and their regulations.

For medicinal or health products which have not been registered or licensed, HSA has not assessed their safety, quality and efficacy.

AUDIT AND LICENSING DIVISION Health Products Regulation Group Health Sciences Authority 11 Biopolis Way #11-01 Helios, Singapore 138667 Email: HSA_Certification@hsa.gov.sg

Group Director

Health Products Regulation Group

Health Sciences Authority

ORIGINAL APPROVAL NO. IMPY2000088

CONDITIONS

- 1 The import shall be made in ONE consignment before the expiry of this approval.
- 2 The consignment shall not be imported through the post.
- This approval is only valid for the importer and may be cancelled at any time by the Authority. It shall be produced for inspection when required by any duly authorised person.
- The copy of the Export Authorisation, if any which accompanies the psychotropic substance shall be forwarded to the Authority, immediately after the importation of the psychotropic substance has been effected.
- The importer shall notify the Authority within seven (7) days of import of the consignment of psychotropic substance stated in the approval, on the actual quantity of the substance imported, and any other related information the Authority may request.
- The importer shall submit yearly returns of stocks of psychotropic substances held as at 31 December of each year to the Authority by 31 January of the following year.

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DUPLICATE
COPY 1
APPROVAL NO.
IMPY2000088

Health Sciences Authority Republic of Singapore

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2 mg of Midazolam base.
Method of Import: AIR

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