Food & Drugs Control Administration

Office of the Commissioner
Block No. 8, 1st Floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State

RETENTION PRODUCT PERMISSION

To,

SWISS PARENTERALS LTD.
808, 809 & 810, KERALA INDUSTRIAL ESTATE, GIDC, NEAR BAVLA, DIST. - AHMEDABAD - 382 220

Reference : Your Application inward ID: **559873** Dated : **04-Feb-2022** (Reg ID : **683682**)

With reference to your Inward application, this is to inform you that your said application is considered & following **RETENTION PRODUCT PERMISSION** has been granted, under the **LICENSE NO. G/28/1078 IN FORM NO. 28** .

Product Section : **Injection**, Product Sub Section : **General Liquid**

Sr. No.	Name of Drugs
1	Prod ID : **272193** Permission Date : **16-August-2017** Type : **Normal** Permission Purpose: **G-General**

Generic Name : **Calcium Folinate Injection USP 10mg/ml, 10ml (For IM/IV use only)** Brand Name : **Calcium Folinate Injection USP 10mg/ml, 10ml**

Composition Title : **Each ml contains**

Composition	Ingredients	Standards	Strength	UOM	Equivalent to
API	Calcium folinate	USP	10	Milligram	Folinic acid
Excipients	Excipients	--	0	Q.S	-----

Product Package Size Details:

Product Size	UOM	Container	Dose	Remark
10	Milliliter(ml)	Glass Vial	Single	

Terms and Conditions

1) Licensee should comply with all the provisions of Drugs & Cosmetics Act, 1940 & Rules 1945 as amended time to time.
2) Licensee should comply with all the provisions of Drugs (Price Control) Order 2013 as amended time to time (wherever applicable).
3) Licensee should abide by all the provision of Drugs & Magic Remedies (Objectionable Advertisement) Act, 1954 & Rules 1955 as amended up to date.
4) Licensee should not manufacture any drug by a name belonging to another manufacturer.
5) Licensee should not manufacture or sell drugs even if it is included in the approved list of product, if it is or as and when banned by Licensing Authority or Drugs Controller General of India or Government of India.
6) The permission is granted subject to the condition that, the product is safe for use in context of pharmaceutical Aids additives and excipients used in the formulation.
7) Any addition thereto or any deletion therefore will not be carried out without permission of Licensing Authority.
8) Above Retention Product Permission is granted based on undertaking with respect to BCS classification and declaration under Form - 51.

(This Document is Digitally Signed)

Manoj Pravinsinhji Gadhvi
(Asstt. Commissioner)
For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar