

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: **559860** Dated : **04-Feb-2022** (Reg ID : **561669**)

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	<p>Prod ID : 341922 Permission Date : 19-Jun-2019 Type : Normal Permission Purpose: G-General</p> <p>Generic Name : TRANEXAMIC ACID INJECTION BP 500 MG/ 5 ML Brand Name : SWINEXAMIC</p> <p>Composition Title : Each ml Contains :</p> <table><thead><tr><th>Composition</th><th>Ingredients</th><th>Standards</th><th>Strength</th><th>UOM</th><th>Equivalent to</th></tr></thead><tbody><tr><td>API</td><td>TRANEXAMIC ACID</td><td>BP</td><td>100</td><td>Milligram</td><td></td></tr><tr><td>Preservatives</td><td>Sodium Metabisulphite</td><td>BP</td><td>1</td><td>Milligram</td><td>-----</td></tr><tr><td>pH adjustant</td><td>Sodium Hydroxide</td><td>BP</td><td>0.6</td><td>Milligram</td><td>-----</td></tr><tr><td>Vehicle/Solvent</td><td>Water for Injection</td><td>BP</td><td>0</td><td>QS</td><td>-----</td></tr></tbody></table> <p>Product Package Size Details:</p> <table><thead><tr><th>Product Size</th><th>UOM</th><th>Container</th><th>Dose</th><th>Remark</th></tr></thead><tbody><tr><td>5</td><td>Milliliter(ml)</td><td>Glass Ampoule</td><td>Single</td><td></td></tr></tbody></table>	Composition	Ingredients	Standards	Strength	UOM	Equivalent to	API	TRANEXAMIC ACID	BP	100	Milligram		Preservatives	Sodium Metabisulphite	BP	1	Milligram	-----	pH adjustant	Sodium Hydroxide	BP	0.6	Milligram	-----	Vehicle/Solvent	Water for Injection	BP	0	QS	-----	Product Size	UOM	Container	Dose	Remark	5	Milliliter(ml)	Glass Ampoule	Single	
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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



Reg ID : **561669**

Doc ID: **PP84160341922**

SWISS PARENTERALS LTD.

License No - **G/28/1078** From Date: **04-Mar-2022** To Date: **03-Mar-2027**

Print Date : **20/06/2022 02:22 PM**

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