

**Form-13**

(See Rule-46)

**MR No.2830-BLR-25-26/PH -5967**

**Certificate of test or analysis by Government Analyst Under Section 25(1) of the
Drugs and Cosmetics Act,1940**

- Name of Inspector from whom received: **Karunadevi,Assistant Drugs Controller
OFFICE OF THE ASST DRUGS CONTROLLER,CA:4/1 SyNo:17,Ground Floor,MSK Compound,
Kalaburgi Circle-ADC2,Kalaburgi-585103**
- Serial No of Inspectors Memorandum : **GL2/REG/CMS/110201/KA-B01** and Date **19-05-2025**
- Number of Sample : **110201**
- Date of Receipt : **07-07-2025**
- Name of drugs purporting to be contained in the sample: **Sodium Bicarbonate Injection IP 7.5%w/v**
Batch No: 240115A Date Of Mfg.:01/2024 Date of Exp: 12/2025
 Quantity: **1x10x10ml ampoules.** Mfg Lic.No. **G/28/1078**
 Mfg. by: **SWISS PARENTERALS LTD ,808,809 & 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Dist: Ahmedabad -
382220, Gujarat, INDIA.**

6. Condition of seals on the package: **Intact & Tally with Specimen Seal**7. Result of test or analysis with protocols of test or analysis applied:**IP 2022.**

In the opinion of the undersigned the sample referred to above **is not of standard quality as defined in the Drugs and Cosmetics Act,1940 and rules thereunder for the reasons given below**

RESULTS

DESCRIPTION: Clear, colorless solution in sealed, transparent glass ampoules, in an ampoule tray, packed in a sealed polythene cover.

IDENTIFICATION : Answers to the test for Sodium salts and Bicarbonates.

pH:	PASSES THE TEST	Found	8.45	IP Limits	7.0 to 8.5
EXTRACTABLE VOLUME:	PASSES THE TEST				
BACTERIAL ENDOTOXIN TEST:	PASSES THE TEST				
STERILITY:	DOES NOT PASS THE TEST				

Assay For	Found	IP Limits
Sodium Bicarbonate	7.64%w/v	7.05%w/v to 7.95%w/v

Reason for declaring Sample as Not of Standard Quality:

The sample has been declared as Not of Standard Quality as it does not conform to IP Standards with respect to Test for Sterility.

Dated:25/08/2025

CC: DC Karnataka

(Manjula G.)

Government Analyst, Karnataka

Note:"Manufacturer's Address on the sample label is stated as "SWISS PARENTERALS LTD., 808,809 & 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Dist: Ahmedabad - 382220, Gujarat, INDIA." whereas, the same is stated as "SWISS PHARMACEUTICALS LTD., 808, 809 & 810, KERALA INDUSTRIAL ESTATE, GDC NR BAVTA. DIST AHMEDABAD - 382220" in the Form-18 sent by the ADC."

Signature Not Verified

Digitally signed by
Date: 2025.08.25 18:23:56
+05:30