± 10.0 % of average fill weight



SRA Satiate Research & Anatech Pvt. Ltd.

NABL ACCREDITED GOVT. APPROVED TESTING LABORATORY Plot No. 264. 1st & 2nd Floor, HSIIDC, Barwala-134118, Panchkula (Haryana) E-mail: satiateresearch@gmail.com, Website: www.sralabs.com

TEST REPORT

FDA Lic. No.: 25-LAB-HR

Mfg. Lic. No

Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

Name of sample : Hydrocortisone Sodium Succinate Injection AR No. : SA/GO-061125/029 IP 100mg **Batch Size** : NM Batch No. : 2125144 D/F : 03/2027 D/M : 04/2025 Name of supplier : Swiss Parenterals Limited **Original Manufacturer** : NM

Ref. No.(As in test request slip) : NM Sample Submitted By : Medical Superintedent ESIC Ref. No.(As given by party) : NM

Address : ESIC Pooluvapatti to Thirumurugan Poondi

Ring Road Tiruppur - 641 603 Tiruppur - 641 Sample Quantity : 30 Nos. Date of receipt : 29/10/2025 Sample received on : 06/11/2025 Date of start of analysis : 06/11/2025 Date of completion of analysis : 20/11/2025 Protocol of test applied : IP 2022 Date of Issue of the report : 20/11/2025

TEST PARAMETERS OBTAINED LIMITS Description : White powder filled in transparent glass vial. Average fill weight : 138.36 mg

Uniformity of weight : Min. Max. Limit -1.31 % +2.63 %

Identification Test A-By IR Complies To comply

B-By TLC : Complies To comply Appearance of solution

(i)-Colour of solution : Complies To comply (ii)-Clarity of solution : Complies To comply : 7.176

(6.50 - 8.00)Related Substances (By HPLC)

Hydrocortisone Impurity : 1.08 % NMT 7.00 % Any other individual impurity : 0.26 % NMT 2.00 %

Particulate Matter Greater than or Equal to 10 µm : 215.00 Particles/Container

NMT 6000 Particles/Container Greater than or Equal to 25 µm : 75 Particles/Container NMT 600 Particles/Container

Bacterial Endotoxins : Less than 1.25 EU/mg NMT 1.25 EU/mg Sterility : Complies To comply Leak test : Complies

To comply **CONTENTS OBTAINED CLAIM** LIMITS METHOD Assay (By UV)

Each vial contains

Page: 1 of 2

Hydrocortisone Sodium Succinate



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TEST REPORT

FDA Lic. No.: 25-LAB-HR

Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

Name of sample : Hydrocortisone Sodium Succinate Injection

IP 100mg

: 2125144 Batch No. D/M : 04/2025

Original Manufacturer : NM

Mfg. Lic. No : NM

Sample Submitted By

Address

Date of start of analysis Protocol of test applied : ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641

: 29/10/2025 : 06/11/2025

: IP 2022

AR No.

Batch Size

D/E

Name of supplier

Ref. No.(As in test request slip) Ref. No.(As given by party)

Sample Quantity Sample received on

Date of completion of analysis

Date of Issue of the report

: SA/GO-061125/029 : NM

: 03/2027

: Swiss Parenterals Limited

: NM : NM

: 30 Nos.

: 06/11/2025 : 20/11/2025

: 20/11/2025

CONTENTS

Date of receipt

Eq. to Hydrocortisone

102.26 mg

: Medical Superintedent ESIC

100.00 mg

(95.00 - 105.00) mg

IP 2022

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

End of Report



Date: 20/11/2025

Person In-charge of Testing Dr Surender Panghal (M.Pharma, Ph.D.) (Quality Manager)

Page: 2 of 2



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TEST REPORT

FDA Lic. No.: 25-LAB-HR

Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

Terbutaline 1.25 mg, Ambroxol 15mg SA/GO-061125/027 Guaiphenesin 50 mg per5ml Syrup with AR. No. Name of Sample

Menthol base NM Batch size BRR011F Batch No. 02/2027 11/2024 D/E D/MName of supplier NM NM Original Manufacturer

NM Ref. No.(As in test req. Slip) NM Mfg. Lic. No Ref. No.(As given by party) NM Sample Submitted By Medical Superintedent ESIC

ESIC Pooluvapatti to Thirumurugan Poondi 06 Nos. Ring Road Tippur-641 603 Trippur-641 Sample quantity Address

06/11/2025 Sample received on 29/10/2025 Date of receipt Date of completion of analysis 10/11/2025 06/11/2025 Date of start analysis 11/11/2025 As per manufacturer's specification. Date of Issue of the report Protocol of test applied

Light pink coloured liquid filled in pink coloured PET bottle. Description

Identification Test (By HPLC) Complies To comply Bromhexine Hydrochloride Complies To comply Terbutaline sulphate Complies To comply Guaiphenesin (3.50 - 5.50)4.751 pН

1.0751 g/ml (1.02 - 1.20) g/ml Weight per ml

Nominal volume 100.0 ml NLT 100.0 ml 100.8 ml Extractable volume

Diethylene glycol & Ethylene

glycol (By GC) NMT 0.10 % Not detected Diethylene glycol NMT 0.10 % 0.001 % Ethylene glycol Complies To comply

TEST PARAMETERS RESULT **CLAIM LIMIT**

Assay:-Composition

15.00 mg (13.50 - 16.50) mg 14.47 mg Ambroxol Hydrochloride IP

1.25 mg (1.125 - 1.375) mg 1.247 mg Terbutaline Sulphate IP (45.00 - 55.00) mg 50.00 mg 49.17 mg Guaiphenesin IP

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

End of Report



Leak test

Person-in charge of testing Dr Surender Panghal (M. Pharma, Ph.D.) (Quality Manager)

Date: 11/11/2025



Satiate Research & Anatech Pvt. Ltd.

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TEST REPORT

FDA Lic. No.: 25-LAB-HR

Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

AR No.

D/E

Batch Size

: SA/GO-061125/028

Name of sample

: MT25-416

: NM

Batch No.

: 05/2028

D/M

: 06/2025

Name of supplier

: Mesmer Pharmaceuticals

Original Manufacturer

: NM

Mfg. Lic. No

Ref. No.(As in test request slip)

: NM : NM

Sample Submitted By

: Medical Superintedent ESIC

: Levetiracetam Tablet IP 500 mg

Ref. No.(As given by party)

Address

: ESIC Pooluvapatti to Thirumurugan Poondi Ring Road Tiruppur - 641 603 Tiruppur - 641

Sample Quantity

: 70 Tablets

Date of receipt

: 29/10/2025

Sample received on Date of completion of analysis : 06/11/2025

Date of start of analysis

: 06/11/2025

: 08/11/2025 : 08/11/2025

Protocol of test applied

: IP 2022

Date of Issue of the report

TEST PARAMETERS

OBTAINED

Description

: Red coloured elongated shaped biconvex film coated tablet having scored line on one side and

plain on other side.

Average weight

681.31 mg

-1.55 %

Uniformity of weight

Min

Max +2.58 % Limit

LIMITS

±5.0 % of average weight

Identification Test

A - By IR

Complies

To comply

B - By HPLC

Complies

To comply

Dissolution test (By HPLC)

Avg

Limit

Max

In water

91.49 %

96.54 %

94.51 %

Q. NLT 80.00 %

Related substances (By HPLC)

Not detected

NMT 0.3 %

Levetiracetam impurities Any other secondary impurities

Not detected

NMT 0.1 %

Total impurities

Not detected

NMT 0.6 %

To comply

Hardness

4.5 kg/cm2 Complies

METHOD

Leak test CONTENTS

OBTAINED

CLAIM

LIMITS

Assay (By HPLC)

Each film coated tablet contains .

Levetiracetam IP

493.25 mg

500.00 mg

(450.00 - 550.00) mg

IP 2022



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TEST REPORT

FDA Lic. No.: 25-LAB-HR

Form-39A, 150-E (f) Report of test or Analysis by Approved Institution For Procurement Agency

: Levetiracetam Tablet IP 500 mg

Batch Size

AR No.

D/F

: SA/GO-061125/028

Batch No.

Name of sample

· MT25-416

D/M

: 06/2025

: NM : 05/2028

Name of supplier

: Mesmer Pharmaceuticals

Original Manufacturer

: NM

Mfg. Lic. No

: NM

Ref. No.(As in test request slip)

: NM

Sample Submitted By

: Medical Superintedent ESIC

Ref. No.(As given by party)

Address

: ESIC Pooluvapatti to Thirumurugan Poondi

Ring Road Tiruppur - 641 603 Tiruppur - 641

Sample Quantity

: 70 Tablets

Date of receipt

: 29/10/2025

Sample received on

: 06/11/2025

Date of start of analysis

Date of completion of analysis

: 08/11/2025

Protocol of test applied

: 06/11/2025

: IP 2022

Date of Issue of the report

: 08/11/2025

In the opinion of the undersigned, the sample referred to above is of Standard Quality as defined in the Drugs and Cosmetics Act and the Rules made under for the reasons given below in respect to Test(s) mentioned above.

End of Report

Date: 08/11/2025

Person In-charge of Testing Dr Surender Panghal (M.Pharma, Ph.D.) (Quality Manager)

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