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ARBRO™
PHARMACEUTICALS PRIVATE LIMITED
Analytical Division

ISO 9001 : 2015 Certified & Govt. Approved Test House
4/9, Kirti Nagar Industrial Area, New Delhi - 110015 (INDIA)
Phone : +91 11-45754575, Email : arbrolab@arbropharma.com, Website : www.testing-lab.com

Form No. : 39A [See rule 150-E(i)]
Approval No.: W 26(8)/LAB

CERTIFICATE OF ANALYSIS

Report No. : A202308240050

Sample : GENPEN 40 (PANTOPRAZOLE GASTRO-RESISTANT TABLETS I.P.)
Mfd. By : GENTECH HEALTHCARE PVT. LTD.
Recd. On : 24/08/2023
Supplied By : NS
Mfg lic. No. : [illegible]
Submitted By : DRUGS CONTROL DEPARTMENT
Ref. No. : 13(17)/MISC/2023/2156,DATE: 22/08/2023
Address : GOVERNMENT OF NATIONAL CAPITAL TERRITORY OF DELHI, F-17,, KARKARDOOMA, DELHI- 110032 INDIA

Batch No	Mfg. Date	Expiry Date	Batch Size	Sample Quantity
GENT5138	12/2022	11/2024	NS	150 Tablets

Sample ID 202308240050 Date of start of analysis 24/09/2023 Date of completion of analysis 05/10/2023

Sample not drawn by laboratory.

Reference to protocol :- IP 2022 (PANTOPRAZOLE GASTRO-RESISTANT TABLETS)
Description : Yellow coloured round biconvex enteric coated tablets
Identification (A) (by HPLC) : Complies.
Identification (B) (by U-V) : Complies

<Parameters>	<Results>	<Lower limit>	<Upper limit>	<Method>
Average Weight	: 161.75 mg	-	-	
Uniformity of weight	: -3.18 % to +2.94 %	-7.50 %	7.50 %	
Dissolution (by HPLC) : (A) Acid Stage	: -0.70 % to +6.88 % .	-	10.0 %	
Dissolution (by HPLC) :- (B) Buffer Stage	: Min-55.14 % to Max-79.13 %, Average-64.57 %	60.0 %	-	

Assay : Each enteric coated tablet contains :

<Contents of>	<Obtd. / Av.wt.>	<Claim>	<Lower limit>	<Upper limit>	<Method>
Pantoprazole Sodium Cal.as Pantoprazole,anhydrous (by HPLC)	: 42.34 mg	40.0 mg	36.0 mg	44.0 mg	IP

Report : In the opinion of the undersigned, the sample referred to above is not of standard quality as defined in the Act and the rules made thereunder for the reason given below:- of : w.r.t Dissolution of Buffer Stage.

To verify Report Scan this Code.

*Terms & Conditions:
(1) Total liability of this laboratory is limited to the invoice amount.
(2) Sample not drawn by the laboratory, unless specified. The results apply to the samples as received.
(3) The results listed refer only to the tested sample and applicable parameter. Endorsement of products is neither inferred nor implied.
(4) This report is not to be reproduced wholly or in part and cannot be used as evidence in the court of Law and should not be used in any advertising media without our special Permission on writing.

Person In Charge
Thursday, Oct 05, 2023
Silpi Kalita
Person In Charge

(10)

FORM – 13
(See Rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS & COSMETICS ACT 1940

CERTIFICATE No. F.2(24)/TR/DTL-228/23 (Revised Report)

1. Name of Inspector from whom received : Mr. AmarKumar Mahavir Mokashi, Drugs Inspector, Govt. of N.C.T of Delhi, DELHI- 110 032.
2. Serial No.and date of Inspector's Memorandum : 19(77)/2023/GADC/87 DT 25/07/2023
3. Number of Sample : AM/21/2023
4. Date of Receipt : 25/07/23
5. Name of Drugs purporting to be contained in the sample : Pantoprazole Gastro-Resistant Tablets IP 40 mg (Compeer 40)
6. Condition of seal on the (Packet or on Portion of sample or container) : Seals were intact & identical to the specimen impression of the seal received from the Drugs Inspector.
7. Result of test or analysis with protocols of test or analysis applied : Please see below.

Regn.No	B.No	D/Mfg.	D/Exp.	Mfg.by
DTL- 228/23	GENT5138	12/2022	11/2024	M/s Gentech Healthcare Pvt. Ltd, 1470, HSIIDC, Rai 131029 (INDIA)

COMPOSITION : Each enteric coated tablet is purported to contain:-
Pantoprazole Sodium IP equivalent to Pantoprazole 40 mg

RESULTS & PROTOCOLS	: As per IP 2022
DESCRIPTION	: Yellow, circular, biconvex, coated tablets packed in aluminium aluminium foil blister strip.
IDENTIFICATION	: Passes the test (Positive for Pantoprazole Sodium)
AVERAGE WEIGHT	: 162.5 mg
UNIFORMITY OF WEIGHT	: Within Limits
DISSOLUTION	: Does not comply with IP

ASSAY : Each coated tablet on an average contains:-

Content of	Obtained	Claim	% of Claim	Limits
Pantoprazole Sodium equivalent to Pantoprazole	41.77 mg	40 mg	104.43	90-110 % of claim

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in The Drugs & Cosmetics Act, 1940 and Rules thereunder for the reason given below:
THE SAMPLE DOES NOT CONFORM AS PER IP WITH RESPECT TO TEST FOR DISSOLUTION.

Date: 26/10/23

Copy to:
The Drugs Controller, Govt. of NCT of Delhi.
4th FLOOR, F-17, KARKARDUMA, DELHI-32

26/10/23
GOVERNMENT ANALYST

OFFICE OF THE GOVT. ANALYST Drug Laboratory Govt. of Delhi

(SHIV RAJ)
Government Analyst
Drugs Testing Laboratory
Govt. of NCT of Delhi

SIMA LABS

Sophisticated Industrial Materials Analytic Labs Pvt. Ltd.

(GOVT. APPROVED TESTING LABORATORIES)

Address : A-3/7, Mayapuri Industrial Area, Ph-II, New Delhi - 110 064
Phone : +(91)-(011) 4385 [illegible]
Email : reports@simalab.co.in
CIN No : U74899DL1986PTC024788
Website : www.simalab.net | www.simalab.com

Approval No.: W(001)/10/Lab

Form 39A

See sub-rule (f) of rule 150E Drugs & Cosmetics Act, 1940 & Rules,1945)

TEST REPORT

Party Code	: D/DLH/19123	REPORT NO	: FTD823000023
* Customer Name & Address	Drugs Control Department (Govt. of N.C.T. of Delhi) F-17, Karkardooma, Delhi-110032	*Customer Ref No.	: 13(175)/Med/2023/2155
		*Reference Date	: 22/08/2023
		Date of Received	: 23/08/2023
		Date of Issue	: 19/09/2023
		Start Date of Analysis	: 23/08/2023
		Date of Completion	: 18/09/2023
*Sample Name	: Levetiracetam Tablets IP 500 mg	*Batch No./Lot No.	: DRT2212-23
		*Batch Size	: NS
*Mfg. by	: Regent Ajanta Biotech	*Sample Qty.	: 300 Tablets
*Mfg. Licence No.	: NS	*Mfg. Date	: 12/2022
*Original Mfg. by	: NS	*Exp. Date	: 11/2024

RESULTS OF ANALYSIS

Reference : IP 2022 Page No 2733 to 2734

Description	: Yellow elongated biconvex scored film coated tablets
Identification	: Complies
Average Weight	: 715.25 mg
Uniformity of Weight	: Within limits (Limit : ± 5%)
Dissolution (By HPLC)	: Does not Complies (Limit : Min 85%) (59.62 to 70.43%)
Related substances (By HPLC)	: Complies
Assay	: Each film coated tablet contains.

S.No.	Parameters	Results	Label Claim	Limit	Protocols
1.	Levetiracetam	502.28 mg 100.46%	500 mg	90 to 110%	IP

Opinion : In the opinion of the undersigned the sample referred to above is NOT OF STANDARD QUALITY as defined in the Act & the Rules made thereunder as per IP, wrt Dissolution test only

--- End of Test Report ---

Rajaram
PERSON IN CHARGE

Remarks:
1. The Results listed refer only to the above tested sample & applicable parameters. Endorsement of products is neither intended nor implied.
2. Liability of laboratory is limited to the invoiced amount only. Any dispute arising out of this report shall be subject to Delhi jurisdiction only.
3. This Test Report is not to be reproduced wholly or in part and cannot be used as evidence in the Court of law and should not be used in any advertising media without written permission from SIMA Labs Pvt. Ltd.
4. The sample(s) of Drugs & Cosmetics will be destroyed after one year, Perishable samples (Other than Drugs & Cosmetics) will be destroyed after 5 days and non perishable samples will be destroyed after 30 days of the date of issue of test report or unless otherwise specified.
5. SIMA Labs Pvt. Ltd. will not be held responsible for the authenticity of any photocopied, forged and or partially presented test reports.
6. SIMA Labs Pvt. Ltd. will ensure all corrective action as per our policy in case of any discrepancy in any sample tested by SIMA Labs Pvt. Ltd.
7. Re-testing charges will be applicable in case the results are reproducible.
8. Duplicate copy will be issued on chargeable basis.
9. This Test Report is not valid without a hologram.
10. SIMA Stands for : Sophisticated Industrial Materials Analytic

Page 1 of 1

SIB

* Indicates details provided by the customer

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FORM – 13
(See Rule 40)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS & COSMETICS ACT 1940

CERTIFICATE No. F.2(24)/TR/DTL-255/23(Revised Report)

1. Name of Inspector from whom received : Mr. Hemant Kumar, Drugs Inspector, Govt. of N.C.T of Delhi, DELHI- 110 032.
2. Serial No.and date of Inspector's Memorandum : 19(54)/2023/GADC/LR/83 DT.09/08/2023
3. Number of Sample : HK/17/2023
4. Date of Receipt : 10/08/23
5. Name of Drugs purporting to be contained in the sample: Levetiracetam Tablets IP 500 mg
6. Condition of seal on the (Packet or on Portion of sample or container) : Seals were intact & identical to the specimen impression of the seal received from the Drugs Inspector.
7. Result of test or analysis with protocols of test or analysis applied : Please see below.

Regn.No	B.No	D/Mfg.	D/Exp.	Mfg.by:
DTL- 255/23	DRT2212-23	12/2022	11/2024	M/s Regent Ajanta Biotech 86-87, Village Makhiyali Dundi, Peerpura Road, Roorkee-247667 (U.K)

COMPOSITION : Each film coated tablet is purported to contain:-
Levetiracetam IP 500 mg

RESULTS & PROTOCOLS	: As per IP 2022
DESCRIPTION	: Yellow, elongated, biconvex film coated tablets scored on one side packed in aluminium foil blister strip.
IDENTIFICATION	: Passes the test (Positive for Levetiracetam)
AVERAGE WEIGHT	: 720.96 mg
UNIFORMITY OF WEIGHT	: Within Limits
DISSOLUTION	: Does not Comply with IP

ASSAY : Each film coated tablet on an average contains:-

Content of	Obtained	Claim	% of Claim	Limits
Levetiracetam	483.43 mg	500 mg	96.89	90-110 % of claim

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in The Drugs & Cosmetics Act, 1940 and Rules thereunder for the reason given below.

THE SAMPLE DOES NOT CONFORM AS PER IP WITH RESPECT TO TEST FOR DISSOLUTION.

N.B: TEST FOR RELATED SUBSTANCES NOT DONE DUE TO TECHNICAL REASONS.

Date: 26/10/23

Copy to:

The Drugs Controller, Govt. of NCT of Delhi.
4th FLOOR, F-17, KARKARDUMA, DELHI-32

26/10/23
GOVERNMENT ANALYST

(SHIV RAJ)
Government Analyst
Drugs Testing Laboratory
Govt. of NCT of Delhi

(B) 2191

FORM - 13

(See Rule 46)

CERTIFICATE OF TEST FOR ANALYSIS BY GOVERNMENT ANALYST UNDER

SECTION 25(1) OF THE DRUGS & COSMETICS ACT 1940

CERTIFICATE No. F.2(24)/TR/DTL-234/23

1. Name of Inspector from whom received	Mr. Ram Kumar Kumhar, Drugs Inspector, Govt. of N.C.T of Delhi, DELHI-110 032.
2. Serial No. and date of Inspector's Memorandum	1989/2023/GADC/100 DT 27/07/2023
3. Number of Sample	RXX/39/2023
4. Date of Receipt	27/07/23
5. Name of Drugs purporting to be contained in the sample.	Amlodipine Tablets IP 5 mg
6. Condition of seal on the (Packet or on Portion of sample or container)	Seals were intact & identical to the specimen impression of the seal received from the Drugs Inspector.
7. Result of test or analysis with protocols of test or analysis applied	: Please see below.

Reqn.No	B.No	D/Mfg.	D/Exp.	Mfg.by
DTL- 234/23	DL2301064	JAN.2023	JUN.2024	M/s Adroit Pharmaceuticals Pvt. Ltd. 46, Ganoda Maitar, Jaipur-6(RJ).

COMPOSITION : Each uncoated tablet is purported to contain:-

Amlodipine Besylate IP equivalent to Amlodipine 5 mg

RESULTS & PROTOCOLS	: As per IP 2022
DESCRIPTION	Pink coloured, biconvex uncoated tablets packed in aluminium foil blister strip.
IDENTIFICATION	: Passes the test (Positive for Amlodipine Besylate)
AVERAGE WEIGHT	: 68.35 mg
UNIFORMITY OF WEIGHT	: Within Limits
DISSOLUTION	: Complies with IP
RELATED SUBSTANCES	: Does not comply with IP

ASSAY : Each uncoated tablet on an average contains:-

Content of	Obtained	Claim	% of Claim	Limits
Amlodipine Besylate equivalent to Amlodipine	4.98 mg	5.0 mg	99.6	90-110% of claim

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in The Drugs & Cosmetics Act, 1940 and Rules thereunder for the reason given below.

THE SAMPLE DOES NOT CONFORM TO IP 2022 WITH RESPECT TO TEST FOR RELATED SUBSTANCES.

Date: 26/10/23

Copy to:

The Drugs Controller, Govt. of NCT of Delhi

4th FLOOR, F-17, KARKARDUMA, DELHI-32

26/10/23

GOVERNMENT ANALYST

OFFICE OF THE GOVT. ANALYST Drug Laboratory Govt. of Delhi

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SIMA LABS
Sophisticated Industrial Materials Analytic Labs Pvt. Ltd.
(GOVT. APPROVED TESTING LABORATORIES)

Address : A-3/7, Mayapuri Industrial Area Ph-II, New Delhi - 110064
Phone : +(91)-(011) 4356 4500
Email : reports@simalab.com
CIN No : U74899DL1987PTC031745
Website : www.simalab.in, www.simalabs.com

Approval No.: W(001)/10/Lab

Form 39A
See sub-rule (f) of rule 150E Drugs & Cosmetics Act, 1940 & Rules,1945

TEST REPORT

Party Code : D/DLH/19123
* Customer Name & Address : Drugs Control Department
(Govt. of N.C.T. of Delhi) F-17, Karkardooma, Delhi-110032

REPORT NO. : [illegible]
*Customer Ref.No. : 18(170)/Misc/2023/2166
*Reference Date : 22/08/2023
Date of Received : 23/08/2023
Date of Issue : 15/09/2023
Start Date of Analysis : 23/08/2023
Date of Completion : 15/09/2023
*Batch No./Lot No. : DL2301004
*Batch Size : NS
*Sample Qty : 100 Tablets
*Mfg. Date : 01/2023
*Exp. Date : 00/2024

*Sample Name : Amlodipine Tablets IP 5 mg
*Mfg. by : Adroit Pharmaceuticals Pvt. Ltd.
*Mfg. Licence No. : NS
*Original Mfg. by : NS

RESULTS OF ANALYSIS

Reference : IP 2022 Page No 1447 to 1448

Description	: Pink coloured round biconvex uncoated tablets.
Identification (By HPLC)	: Complies
Average Weight	: 68.88 mg
Uniformity of content (By HPLC)	: Within limits (Limit : 85.0% to 115.0% of average value) (92.28% to 110.06%)
Dissolution (By UV)	: Complies (Limit : Min 80.0%) (87.72% to 107.85%)
Related substances (By HPLC)	: -
Impurity D	: 6.51% (Limit : Max. 0.5%)
The Sum of areas of all other Secondary peaks	: 15.77% (Limit : Max. 0.5%)
Assay (By HPLC)	: Each uncoated tablet contains

S.No.	Parameters	Results	Label Claim	Limit	Protocols
1.	Amlodipine besylate Eq.to Amlodipine	4.853 mg 97.06%	5.0 mg	90.0% to 110.0%	IP

Opinion : In the opinion of the undersigned the sample referred to above is NOT OF STANDARD QUALITY as defined in the Act & the Rules made thereunder as per IP, wrt, Related Substances

--- End of Test Report ---

PERSON IN-CHARGE

Remarks: 1. The Results listed refer only to the above tested sample & applicable parameters. Endorsement of products is neither inferred nor implied.
2. Liability of laboratory is limited to the invoiced amount only. Any dispute arising out of this report shall be subject to Delhi jurisdiction only.
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4. The sample(s) of Drugs & Cosmetics will be destroyed after one year, Perishable samples (Other than Drugs & Cosmetics) will be destroyed after 7 days and non perishable samples will be destroyed after 30 days of the date of issue of test report or unless otherwise specified.
5. SIMA Labs Pvt. Ltd. will not be held responsible for the authenticity of any photocopied, forged and or partially presented test reports.
6. SIMA Labs Pvt. Ltd. will ensure all corrective action as per our policy in case of any discrepancy in any sample tested by SIMA Labs Pvt. Ltd.
7. Re-testing charges will be applicable in case the results are reproducible.
8. Duplicable copy will be issued on chargeable basis.
9. This Test Report is not valid without a hologram.
10. SIMA Stands for : Sophisticated Industrial Materials Analytic.

Page : 1 of 1
SS

* Indicates details provided by the customer

DROIT PHARMACEUTICALS PVT.LTD.
46, Garoba Maidan, NAGPUR-440 008

CERTIFICATE OF ANALYSIS

See Rule 150E.(f) Drug M.Lic.No.766/508
CHEMICAL & MICROBIOLOGICAL

Name of Product: AMLODIPINE TABLETS I.P. 5MG
EACH TABLET Contains :AMLODIPINE BESYLATE I.P.:5MG

BATCH NO :DL2301064
BATCH SIZE :4700000 Tablets
MFG Dt :January'2023
EXP DATE :June'2024
ANALYSED as Per :AS PER I.P

Qty Sampled :10X10 TABLET
Sampled on :04/02/2023
TEST REPORT NO.F/2302012-M
DATE OF REPORT:09/02/2023

PROTOCOLS OF THE TESTS APPLIED

S.NO	TEST	STANDARD	RESULT	REMARKS
1	DESCRIPTION	PINK ROUND SLIGHTLY BICONVEX UNCOATED TABLET.		
2	IDENTIFICATION	AS PER I.P.	COMPLIES	PASSES
3	UNIFORMITY OF WEIGHT	AS PER I.P.	COMPLIES	PASSES
4	AVERAGE WEIGHT	0.0600- 0.0740gms	0.0678gms	PASSES
5	HARDNESS	2.0000- 6.0000Kg/Cm²	2.5000Kg/Cm²	PASSES
6	FRIABILITY	NMT 1.0000%	0.2490%	PASSES
7	RELATED SUBSTANCES	AS PER I.P.	COMPLIES	PASSES
8	DISSOLUTION	070.000,000.000	89.80-105.45	~~FAIL~~
9	UNIFORMITY OF CONTENT	85.0000-115.000%	92.7200%	~~PASSES~~
10	LEAK TEST	AS PER SOP	COMPLIES	PASSES
11	ASSAY Contains	90.0000-110.000% of Stated Amt of AMLODIPINE	99.9800% of Lab.amt of AMLODIPINE	PASSES
12	TOTAL AEROBIC MICROBIAL COUNT	NMT 2000 CFU/GM	21CFU/GM	PASSES
13	TOTAL COMBINED YEAST/MOLD CONT	NMT 200 CFU/GM	9CFU/GM	PASSES
14	E.COLI	ABSENT	ABSENT/gm	PASSES

OPINION :In The Opinion Of The Undersighed The Sample Referred To Above Is OF STANDERD QUALITY As Defined In The Act & Rules Made There Under In Above Respect.

ANALYST MICROBIOLOGY INCHARGE CHEMICAL INCHARGE

DRUGS CONTROL DEPARTMENT
GOVT OF NCT OF DELHI
3418
DATED 06 OCT 2023

ARBRO™
PHARMACEUTICALS PRIVATE LIMITED
Analytical Division
ISO 9001 : 2015 Certified & Govt. Approved Test House
4/9, Kirti Nagar Industrial Area, New Delhi - 110015 (INDIA)
Phone : +91 11-45764575, Email : arbrolab@arbropharma.com, Website : www.testingarbro.com

Form No. : 39A [See rule 150-E(f)]
Approval No.: W 26(8)/LAB

CERTIFICATE OF ANALYSIS

Report No. : A202308240016

Sample	: CIPRIN - 500 (CEPHALEXIN CAPSULES IP)		
Mfd. By	: JACKSON LABORATORIES PVT. LTD.	Rcd. On	: 26/08/2023
Supplied By	: NS	Mfg lic. No.	: [illegible]
Submitted By	: DRUGS CONTROL DEPARTMENT	Ref. No.	: [illegible]/2023/2156,DATE 22/08/2023
Address	: GOVERNMENT OF NATIONAL CAPITAL TERRITORY OF DELHI, F-17,, KARKARDOOMA, DELHI-110032 INDIA		

Batch No	Mfg. Date	Expiry Date	Batch Size	Sample Quantity
C-6699	03/2023	02/2025	NS	100 Capsules

Sample ID 202308240016 **Date of start of analysis** 26/08/2023 **Date of completion of analysis** 23/09/2023

Reference to protocol	:- IP 2022 (CEPHALEXIN CAPSULES)				
Description	: Grey and yellow unsealed hard gelatin capsule containing white powder.				
Identification (A) (by I.R)	: Complies				
Identification (B) (by HPLC)	: Complies.				
Related Substances (by TLC)	: Complies				
<Parameters>		**<Results>**	**<Lower limit>**	**<Upper limit>**	**<Method>**
Average Weight	: 636.6 mg		-	-	
Average fill	: 540.2 mg		-	-	
Uniformity of weight	: -1.83% to +1.41 %		-7.50 %	7.50 %	
Dissolution (by U-V)	: Min.6.74% to Max.46.34% Mean-17.18 %		80.0 %	-	
Water	: 6.84 % w/w		-	10.0 % w/w	
Assay	: Each capsule contains :				
<Contents of>	**<Obtd. / Av.wt.>**	**<Claim>**	**<Lower limit>**	**<Upper limit>**	**<Method>**
Cephalexin,anhydrous (by HPLC)	: 461.11 mg	500.0 mg	460.0 mg	550.0 mg	IP

Report : In the opinion of the undersigned, the sample referred to above is not of standard quality as defined in the Act and the rules made thereunder for the reason given below:- of : w.r.t Dissolution.

To verify Report Scan this Code.

*Terms & Conditions:
(1) Total liability of this laboratory is limited to the invoice amount.
(2) Sample not drawn by the laboratory, unless specified. The results apply to the samples as received.
(3) The results listed refer only to the tested sample and applicable parameter. Endorsement of products is neither inferred nor implied.
(4) This report is not to be reproduced wholly or in part and cannot be used as evidence in the court of Law and should not be used in any advertising media without our special Permission on writing.

Person In Charge
Saturday, Sep 23, 2023
Silpi Kalita
Person In Charge

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(5)

CATTS LABS & RESEARCH PVT. LTD.

AN ISO 9001 : 2015 CERTIFIED Multi Disciplinary Govt. Approved Analytical Laboratory

Trusted Analytical & Research House

Approval No. : S(DD1)/17/Lab

Form 39A

(Rule - 150 E (i) The Drugs & Cosmetics Act, 1940)

F.39F-01(A)

Certificate of Analysis

PARTY CODE : D/DLH/076

PARTY : GOVERNMENT OF NATIONAL CAPITAL TERRITORY OF DELHI
DRUGS CONTROL DEPARTMENT
F-17, KARKADOOMA, DELHI-110032

SAMPLE : DEXAMETHASONE TABLETS IP 4 MG

REPORT NO.: CDR01102308

Lic. NO. : -

MFD. BY : MEDICAMEN ORGANICS LTD

BATCH NO. : MOT12533

SUPP. BY : NS

DT. RECD. : 23-08-2023 DT. MFD. : 01/2023

SAMPLE QTY: 100 TABLETS

RESULTS OF ANALYSIS

Reference : IP 2022, Page 2046-2047

Description	: White round biconvex uncoated tablets.	
Identification	: Conforms to the test	
Average Weight	: 174.9 mg	
Uniformity of Content	: 2.97 to 3.36 mg Within Limits	
Disintegration Time	: 5 to 6 Minutes	Limit: Max. 15 Minutes
Related Substances	: Conforms to the test	

Assay

Each tablet contains,

	Results	Claim
Dexamethasone	: 3.25 mg	4 mg

DRUGS INSPECTOR (HQ)
GOVT OF NCT OF DELHI
DIARY NO. 3806
DATED 5 - OCT 2023

Date of performance : 23/08/2023 to 05/09/2023

NOT OF STANDARD QUALITY

IN THE OPINION OF THE UNDERSIGNED THE SAMPLE REFERRED TO ABOVE
IS NOT OF STANDARD QUALITY
AS DEFINED IN THE ACT & THE RULES THEREUNDER
as per IP wrt Assay test

Person Inc. /Auth. Signatory
(J.S.CHADHA)

DATE 05-09-2023

Page 1 of 1

NOTE: 1. Sample not drawn by us.
2. Results listed refer only to the tested sample & applicable parameters. Endorsement of product is neither covered nor implied.
3. Samples will be destroyed after one month from the date of issue of test certificate unless otherwise specified.
4. Liability of laboratory is limited to the invoiced amount only. Any dispute arising out of this report shall be subject to Delhi jurisdiction only.
5. The Report shall not be reproduced either in full or part without the written approval of laboratory.

Works/Business : S-78, 1st Floor, Okhla Industrial Area, Phase-2, New Delhi-20. Regd. Off. : 496, Sector-21C, Faridabad, Haryana-121001
Tel. : 011-41006737, CIN : U74999HR2016PTC064858, E-mail : labs.faridabad@cattslabs.com Website : www.cattslabs.com

CATTS

J.S.CHADHA

Regional Drugs Testing Laboratory
Sector 39-C, Chandigarh (India) - 160036
Fax : 0172-2638316 Phone No.0172-2668236
Email:rdtlchd@cdsco.nic.in

FORM 13

(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received : Sunil Sethi,Drugs Inspector
Delhi
Drugs Control Department, F-17, Karkardooma, Delhi 110 032.

2. Serial No. and date of Inspector's memorandum : 19(73)/2023/DADC/LR/82 07-AUG-2023

3. Number of Sample : SS/34/23

4. Date of receipt : 21-AUG-2023

5. Names of drugs purporting to be contained in the sample : Dexamethasone Tablets IP 4 mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/CHD/2023-24/28568	CHD/LS/2023-24/1131	MOT22533	Jan-2023	Dec-2024	MEDICAMEN Organics Limited, Plot No. 61, Sector-8A, IIE, SIDCUL, Haridwar-249403 (Uttarakhand)

6. Condition of seals on [the packet or on portion of sample or container] : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below

COMPOSITION : Each uncoated tablet is purported to contains:
Dexamethasone IP 4 mg

Protocol Applied : IP 2022

Sr No.	Test Name	Result	Units
1	Description	White, round, biconvex, uncoated tablet. Packed in blister pack.	NA
2	Identification by IR	(A) Complies with IP	NA
3	Identification by HPLC	(B) Complies with IP	NA
4	Identification by Chemically	(C) Complies with IP	NA

	Average weight	173.95 mg	NA
	Uniformity of content	Complies with IP	85 to 115 %
7	Disintegration test	Complies with IP	NMT 15 minutes
8	Related Substances	Complies with IP	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Reference / Method
1	Dexamethasone	3.928 mg	4 mg	98.20 %	90 to 110 %	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, 1940, and Rules there under for the reasons given below:-

The sample conforms to claim as per IP 2022 in respect of test performed.

Date: 02-NOV-2023

GOVERNMENT ANALYST

END OF REPORT

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