Fwd: Not of standard Quality Tab.Nifedipine Sustained Release IP 20 mg

rc-hqrs < rc-hqrs@esic.gov.in >

DMC RC < dmc-rc@esic.gov.in >

Mon, 06 Apr 2026 10:27:01 AM +0530

To "RC Cell"<rc-hqrs@esic.gov.in>

========== Forwarded message ==========
From: CMS VADODARA <cms-brd.gj@esic.gov.in>
To: "DMC RC"<dmc-rc@esic.nic.in>
Cc: "Daksha Vaja"<pur-dms.gj@esic.nic.in>
Date: Sat, 04 Apr 2026 17:37:11 +0530
Subject: Not of standard Quality Tab.Nifedipine Sustained Release IP 20 mg
========== Forwarded message ==========

Respected Sir,
Please find the attachment

Regards,
Dr. Piyush B. Sheth
CMS Incharge
Vadodara.

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2 Attachment(s)

Tab.Nifedipine Sustained Rele…
10 KB

Tab.Nifedipine 20 mg Test Rep…
999 KB

2041

BY REG. A.D.

hand delivery

NO.VAD/329344/NS
Office of the Joint Commissioner/Assistant Commissior
Food & Drugs Control Administrat
C/O Food & Drugs laborato
Nr. PolyTechr
Vadod
Date:02/04/2(

04 APR 2026

To,

CENTRAL MEDICAL STORES
E.S.I.S
GOTRI ROAD
VADODARA

Sub.: Drugs & Comestics Act, 1940 & Rules thereunder.

Ref.: Form No. 17 Dated 25/09/2025
NIF-20 SR
Batch no. NR019
Mfged. By NABROS PHARMA PVT LTD

Sir,

I, have to state that sample of **NIF-20 SR** Batch no. **NR019** Mfged. By **NABROS PHARMA PVT LTD**, N.H.No.8, ,KHEDA , KHEDA was picked up from your premises for test and analysis.The Government Analyst, has reported the sample in question to be of **NOT OF STANDARD QUALITY** vide his Test Report No. **q1-2174-26** Dt. **30/03/2026**.(Test Rpt No : NSQ/BDL/329344/2026)

Original Test Report is enclosed herewith.

1.You are therefore asked to **STOP SALE / DISTRIBUTION** of the product & recall all the stock of the subject dru sold / distributed immidiately.

2.You are asked to return this product to the supplier under intimation to this Office.

3. As per Section 18A , 22(1) (cca) of said Act you are hereby required to furnish the information along with certified photo copies of document vide which you have acquired / distributed / sold the said drugs within 3 days of tl receipt of this letter.

Remarks: The sample does not conforms to the standard laid down for Nifedipine sustained release Tablets in IP 2022 with respect to Dissolution. (in Acid Stage).
Reasons: Dissolution

Yours Faithfully

Food & Drugs Control Administration
Vadodara

No. FDL/AR/ 2433 /2026
Food & Drugs Laboratory, Vadodara.
Dated:..... 2026

From :
THE GOVERNMENT ANALYST,
Food & Drugs Laboratory,
Vadodara-390 002.

30 MAR 2026

To,
N. M. Malani,
Drugs Inspector,
C/O Food & Drugs laboratory,
Nr. Poly Technic, Vadodara,
Vadodara.

2.4.26.
1601

Report No. : Q-1/174/2026 (ESIS)

FORM – 13
(See Rule 46)
Certificate of test or analysis by Government Analyst under Section 25 (1) of the Drugs and Cosmetic Act, 1940

1. **Name of Inspector from whom received** : N. M. Malani,
2. **Serial No. and date of Inspector's Memorandum.** : VAD/Regular/Emp. State Insurance/ 329344/GJ-BDL Date :- 30/09/2025
3. **Number of Sample** : 1 x 5 x 10 Tablets
4. **Date of receipt** : 01/10/2025
5. **Name of drugs purporting to be contained in the sample:-** NIF-20 SR TAB., Manufactured in India by:- Nabrose Pharma Pvt Ltd. N. H. No 8 Kheda 387411 India.
6. **Condition of seals on the packet or on portion of samples or container:-** Seals were intact & identical With the specimen impression of the seal received separately from Drugs Inspector.
7. **Results of test or analysis with protocols of test or analysis applied:-** Is attached. In the opinion of the Undersigned the sample referred above.

~~Is of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules there under~~
Is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules there under for the reasons given below:-

The sample **does not** conforms to the standard laid down for "Nifedipine sustained-release Tablets" in IP 2022 with respect to Dissolution (In acid stage)

FOOD & DRUGS LABORATORY VADODARA

(Mr. P. J. Parmar)
Government Analyst.
Page No. I of II.

Date : 30 MAR 2026
Hetal

"Test Report"

REPORT NO. : Q-1/ 2174 /2026 (ESIS) **SAMPLE NO. :119/25**

"NIF-20 SR TAB"

Results of the tests or analysis with protocols of test or analysis applied:-

Outer label : NIL

Container label : Nifedipine Sustained Release Tablets IP 20 mg
NIF-20 SR
Composition
Each film coated sustained release tablet contains-
Nifedipine IP 20 mg
Color : Sunset yellow FCF
Excipients q.s.
Store in a cool , dry & dark place.
ESI supply not to be sold.
Mfg. Lic. No.:- G/1355 B. No. :- NR019
Mfg. Date.:- 08/2025 Exp. Date.:- 07/2028
Manufactured in India by:- Nabrose Pharma Pvt Ltd.
N. H. No 8 Kheda 387411 India.

For the following tests and assay methods given in I.P. 2022 under "Nifedipine Sustained - release Tablets" Page No. 3064 are followed.

Description	:	Orange colored circular, biconvex coated tablet.
Content	:	10 Tablets per strip. (05 strip)
Identification	:	Complies with the test for Identification.
Average weight of tablet	:	0.1010 gm
Dissolution	:	**Not Within IP 2022 Limits.** (In acid stage tablet not release between 25 to 45 percent)

Assayed for Nifedipine Content:-

Nifedipine ($C_{17}H_{18}N_2O_6$)	:	20.61 mg per average weight of tablet. (i.e. 103.05 percent of the claim made)

[I.P. 2022 Limits:- Nifedipine Prolonged-release Tablets contains not less than 90.0 percent and not more than 110.0 percent of the stated amount of Nifedipine, $C_{17}H_{18}N_2O_6$]

Checked by: ASR

FOOD & DRUGS LABORATORY VADODARA

(Mr. P. J. Parmar)
Government Analyst
Page No. II of II

..... **End of the report** .....

Disclaimer: This report refers only to a particular sample submitted for testing, Laboratory is not involved in sampling, **Address**: Food & Drugs Laboratory, Near Polytechnic, Nizampura-390002, Vadodara.