

**GOVERNMENT OF ANDHRA PRADESH  
INSURANCE MEDICAL SERVICES DEPARTMENT**

**From**  
The Nodal Officer,  
CDS-2,  
RAJAMAHENDRAVARAM.

**To**  
All the Incharge Medical Officer,  
ESI Dispensaries Under jurisdiction of  
Central Drug Stores-2,  
RAJAMAHENDRAVARAM.

**Rc.No:40/CDS-2/ESIH/RJMVM/2026.Dt: 20-01-2026**

**Sub:** Insurance Medical Services Dept- CDS-2, Rajamahendravaram – Non- Standard Quality (NSQ) Medicine i.e Tab. Ondansetron 8 mg (ONDOC-8)– Return of stock– Regarding.

**Ref:** Rc.No: SA/82/PK/DI/DAC/RJY/U/EG/2025 Dt: 19-01-2026 of O/o. Drug Inspector (FAC), Drug Control Administration, E.G, Rajamahendravaram.

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It is to inform that the following drug has identified as **Non-Standard Quality (NSQ) Medicine** and same was communicated vide reference cited above. (Copy is herewith enclosed)

| Sl. No | Name of the Drug         | Batch No | Date of MFG | Date of Expiry | Remarks |
|--------|--------------------------|----------|-------------|----------------|---------|
| 1.     | Tab. Ondansetron IP 8 mg | F510767A | 09-2025     | 08-2027        | -       |

In this regard, **All the dispensaries under CDS-2, Rajamahendravaram** are hereby instructed to **return the above-said NSQ medicine stock** available at your respective dispensaries to **CDS-2, Rajamahendravaram immediately**, without any further issue to patients.

This matter may be treated as **Most Urgent** and **strict compliance** is requested.

**Encl: Drug Analysis Report.**

**Yours faithfully,**

  
Nodal Officer

CDS-2, Rajamahendravaram  
20/01/26

Copy submitted to the Director, Insurance Medical Services, A.P, Vijayawada for information.

**GOVERNMENT OF ANDHRA PRADESH**  
**DRUGS CONTROL ADMINISTRATION**

From  
 NVVS Kalyani P,  
 Drugs Inspector (FAC)  
 Rajamahendravaram Urban  
 Drugs Control Administration,  
 East Godavari District

To  
 ✓ V. Kamala  
 Pharmacy Officer,  
 M/s Main Stores,  
 ESI Hospital,  
 Rajamahendravaram 533103  
 East Godavari District

Rc.No.SA/82/PK/DI/DCA/RJY/U/EG/2025      dated: 19/01/2026

Sir,

**Sub:** Drugs & Cosmetics Act, 1940 and rules made thereunder – ONDOC-8 (ondansetron Tablets IP 8 mg), B.No.F510767A, MFG.09/2025, EXP.08/2027, Manufactured in India by: M/s Morepen Laboratories Ltd, Unit-V, Plot No.12-c, Sector-2, Parwanoo, Dist. Solan (H.P.) – 173 220 – Declared as **Not of Standard Quality** – Copy of analytical report furnished U/s Sec.25(2) – Disclose source of supply U/s.18-A – Furnish Records and registers as per Sec. 22(1)(cca) of Drugs & Cosmetics Act, 1940– request regarding.,

**Ref:** (1) Form 17 Dt: 23-12-2025 issued to you.

(2) Form 18 bearing S.No. of Memorandum SA/82/PK/DI/DCA/RJY/U/EG/2025 Dt: 23-12-2025 addressed to the Government Analyst, Drugs Control Laboratory, Vijayawada

(3) Form-13 Report No. 152/KYG/APSDDL/2025 dated: 12/01/2026 of the Government Analyst, Drugs Control Laboratory, Vijayawada received on 19-01-2026.

\* \* \* \* \*

It is to inform you that the sample ONDOC-8 (ondansetron Tablets IP 8 mg), B.No.F510767A, MFG.09/2025, EXP.08/2027, Manufactured in India by: M/s Morepen Laboratories Ltd, Unit-V, Plot No.12-c, Sector-2, Parwanoo, Dist. Solan (H.P.) – 173 220 was taken for analysis from your stores vide ref 1<sup>st</sup> cited and the same was sent to the Government Analyst, Drugs Control Laboratory, Vijayawada vide ref 2<sup>nd</sup> cited for analysis.

The subject drug was declared as **Not of Standard Quality** as "The sample fails in Dissolution Test at S1 and S2 level for Ondansetron as per

LP.\* by the Government Analyst, Drugs Control Laboratory, Vijayawada vide ref 3<sup>rd</sup> cited.

In this connection a copy of analytical report of the Government Analyst, Drugs Control Laboratory, Vijayawada of the subject drug is herewith furnished as per Sec.25(2) of Drugs & Cosmetics Act.1940.

In this regard, you are requested to

- i. To stop further distribution of the said batch drug.
- ii. To recall the drug from stores to which the subject drug was distributed.
- iii. To disclose Name, Address and other particulars from whom you have acquired the subject drug as per provision laid down u/s **Sec.18-A** of Drugs & Cosmetics Act 1940
- iv. To furnish certified copies of purchase invoices of the subject drug, distribution particulars of the subject batch drug as per **Sec. 22(1)(cca)** of the Act.
- v. To furnish stock position of the subject drug.

Hence you are requested to furnish required information/records/registers duly attested by the person responsible within 3 days from the date of receipt of this letter.

Yours faithfully

P. *[Signature]* 19/01/2026

Drugs Inspector (FAC)  
Rajamahendravaram Urban

Encls:

1. Original Analytical Report in Form-13, bearing report No. 152/KYG/APSDTL/2025 dated: 12/01/2026 of the Government Analyst, Drugs Control Laboratory, Vijayawada

Copy submitted to:

The Director General, DCA, Govt of AP for favour of information.  
The Deputy Director, DCA, Eluru for favour of information.  
The Assistant Director, DCA, East Godavari District for favour of information.  
M/s Morepen Laboratories Ltd, Unit-V, Plot No.12-c, Sector-2, Parwanoo, Dist. Solan  
(H.P.) – 173 220

**GOVERNMENT OF ANDHRA PRADESH  
DRUGS CONTROL ADMINISTRATION**

**Laboratory No: 1118/H/2025,**

**Date: 12/01/2026**

**Sub:** Drugs and Cosmetics Act, 1940 and Rules Made there under – Analysis of Sample of **ONDOC-8** (Ondansetron Tablets I.P.8 mg), **B.NO:F510767A M.D:09/2025, E.D: 08/2027. Manufactured in India by: M/s. MOREPEN LABORATORIES LTD.,** Unit-V, Plot No.12-C, Sector-2, Parwanoo, Distt. Solan (H.P.)-173 220.

**Ref:** Sl. No. of Memorandum SA/82/PK/DI/DCA/RJY/U/EG/2025, Dated: 23/12/2025. of the Drugs Inspector, Rajamahendravaram (Urban), FAC, E.G. Dist..

The sample received vide reference cited has been analysed and result of the same is enclosed.

*[Signature]*  
**GOVERNMENT ANALYST**

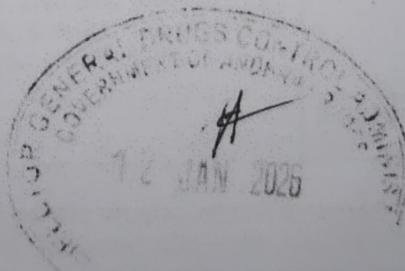
**K. YADAGIRI**  
M.Sc., LL  
Senior Scientific Officer & Government Analyst  
Govt. of Andhra Pradesh  
Drugs Control Laboratory  
Vijayawada-520 008. A.P.

**To:**

The Drugs Inspector, Rajamahendravaram (Urban), FAC, E.G. Distt..

**Copy to:** The Director General, D&C, Drugs Control Administration, Vijayawada, A.P., .

**Copy to:** The Drugs Controller General (India), New Delhi.



FORM - 13  
(See Rule-46)

**DRUGS AND COSMETICS RULES, 1945**  
**CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST**  
**UNDER SECTION 25(1) OF DRUGS AND COSMETICS ACT, 1940**

1. **Name of the Inspector from whom received** P.N.V.V.S, Kalyani Drugs Inspector, Rajamahendravaram (Urban), FAC, E.G. Dist.  
SA/82/PK/DI/DCA/RJY/U/ EG/2025, Dated: 23/12/2025.
2. **Serial Number & date of Inspector's memorandum**
3. **Number of sample** 1118/H/2025  
26/12/2025
4. **Date of Receipt**
5. **Name of drugs purporting to be contained in the sample** ONDOC-8 -(Ondansetron Tablets IP 8 mg )  
  
B.NO: F510767A, M.D: 09/2025, E.D: 08/2027  
Manufactured in India by: M/s . MOREPEN LABORATORIES LTD., Unit-V, Plot No.12-c, Sector-2, Parwanoo, Distt. Solan (H.P.)-173 220.
6. **Conditions of seals on the package** SEALS INTACT AND IDENTICAL WITH THE SPECIMEN SEAL.  
As per I.P.
7. **Result of test or analysis with protocols of the test applied**  
**Composition**  
Each film coated tablet Contains:  
Ondansetron Hydrochloride IP  
Equivalent to Ondansetron 8 mg  
Excipients q.s.  
Colour : Red Oxide of Iron & Titanium Dioxide IP

| TESTS DONE                                 | FOUND   | CLAIM          | LIMITS  | Complies/ Not Complies |
|--|---|----------------|---|------------------------|
| Quantity Received                          | 1x5x10 Tablets  | 1x5x10 Tablets | --  | --                     |
| Description                                | Brick red coloured, Circular & biconvex uniform tablets.  | --             | --  | Complies               |
| Identification                             | Positive for Ondansetron as per I.P.  | --             | --  | Complies               |
| Average Weight                             | 0.1039 gm   | --             | --  | --                     |
| Uniformity of Content                      | 7.95 mg   | --             | 6.75 mg-9.14 mg   | Complies               |
| Dissolution Test for Ondansetron as per IP | <p><b>Stage-I-(S1)</b>-(1)64.12%,(2) 67.03%, (3) 59.07%, (4) 57.85%, (5) 70.09% (6) 61.67%. <b>Average of 6 Units= 63.30%</b>-All units are less than D+5% i.e , 70+5% (75%) as per I.P.</p> <p><b>Stage-II- (S2)</b>-(7)52.39%, (8) 70.83%, (9) 53.78%, (10)69.45%, (11)76.52% (12)47.01%. <b>Average of 12 Units= 62.48%</b>. <b>Average of 12 units are less than D, i.e., 70% and 3 units are less than D-15% i.e., 70-15=55%</b></p> | --             | <p><b>Acceptance Criteria as per IP</b></p> <p>1. S1- Each unit is not less than D+5 per cent</p> <p>2. S2 -Average of 12 units (S1+S2) is equal to or greater than D, and no unit is less than D-15%</p> | Not Complies           |
| Assay for Ondansetron Ref: as per IP       | 7.88mg  | 8 mg           | 7.6-8.4 mg  | Complies               |

In the opinion of the undersigned the sample referred to above is of **NOT OF STANDARD QUALITY** as defined in the Drugs and Cosmetics Act, 1940 and rules there under for the reasons given below:

"The Sample fails in **Dissolution Test** at S1 and S2 level for Ondansetron as per I.P.

Date: 12/01/2026

GOVERNMENT ANALYST