



भारत सरकार / Government of India

केंद्रीय औषध मानक नियंत्रण संगठन / Central Drugs Standard Control Organization  
आंचलिक कार्यालय, सी. डी. एस. सी. ओ. भवन, हैदराबाद / Zonal Office, CDSCO BHAVAN, Hyderabad,  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare,  
स्वास्थ्य सेवा महानिदेशालय / Directorate General of Health Services,  
एस.आर. नगर, हैदराबाद - ५०००३८ / S.R. Nagar, Hyderabad - 500038.  
Certified for IMS (ISO-9001:2015, ISO-14001:2015, ISO 45001:2018)

BY POST

File Ref: 6-2(1)/RL/NSQ-01/HZ/2025-26/1180

Date: 04/11/25

To

Dr. Sai Savya, Store in-charge  
ESIC Medical store,  
Admin block, Sanath Nagar,  
Hyderabad, Telangana- 500038.

**Subject: Testing of "Paracetamol Tablets IP 500 mg," B.No: BTH-19, D/M: 01.02.2025, D/E: 31.01.2027, Manufactured by: M/s. Bengal Chemicals And Pharmaceuticals, E-35 Industrial Area Haridwar-249401 UK declared as Not of Standard Quality bearing sample No. LS/RL/HZ/2025-09/001- Regarding.**

**Reference:**

1. Sample drawn in Form 17 on dated 26/09/2025 from Dr. Sai Savya, Store in-charge, ESIC Medical store, Admin block, Sanath Nagar, Hyderabad, Telangana- 500038.
2. Form-13 test report No: HYD/LSGS/2025-26/42 (CDTLH/0760/F-0457/2025-26) dated 30.10.2025 issued by Government Analyst, CDTL, Hyderabad received by this office Vide inward No. 943 dt 04/11/2025.

Sir/Madam,

With reference to the subject cited above, it is to state that the drug sample "Paracetamol Tablets IP 500 mg," B.No: BTH-19, D/M: 01.02.2025, D/E: 31.01.2027, Manufactured by: M/s. Bengal Chemicals And Pharmaceuticals, E-35 Industrial Area Haridwar-249401 UK was drawn by the undersigned under the provision of Drugs & Cosmetics Act, 1940 in Form 17 dated 26-09-2025 from ESIC Medical Stores, Admin block, Sanath Nagar, Hyderabad, Telangana- 500038.

The said drug sample upon testing has been declared as "Not of Standard Quality" [as defined in Drugs act, 1940 and rules thereunder] in Form 13 by Government Analyst, CDTL, Hyderabad vide Test Report No. HYD/LSGS/2025-26/42 (CDTLH/0760/F-0457/2025-26) dated 30.10.2025 as the sample **does not conform to I.P. 2022 specification with respect to the "test for dissolution only"**

Therefore, under section 18-A (read with section 24) & 22 (1) cca of Drugs & Cosmetics Act 1940, you are requested to disclose the name, address and other particulars of the person from whom you have procured the alleged drug of subject batch (BTH-19) with current stock details of the drug along with supportive documents (Invoice/Challan copy) of same batch to the undersigned.

Further, you are advised to stop usage of the said drug product of subject batch (Batch No.: BTH-19).

This is to be treated as most urgent and you are requested to reply to this office within 07 days from the receipt of this letter by Fax/ E-mail/ Post.

Yours Faithfully,

*T. Rajyalakshmi*

(Teku Rajya Lakshmi)  
Drugs Inspector,  
CDSCO, Hyderabad.

**Enclosures:** As above along with original copy of test report of Government Analyst, CDTL, Hyderabad report No. HYD/LSGS/2025-26/42 (CDTLH/0760/F-0457/2025-26) dated 30.10.2025.





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 : Mrs. Teku Rajya Lakshmi  
Hyderabad Zone CDSCO, Zonal office, Hyderabad ,  
CDSCO BHAVAN, Beside T.B. & Demonstration  
Centre, S.R. Nagar, Hyderabad - 500038, AP (India) -
2. Serial No. and date of Inspector's memorandum : 6-2(1)/HZ/2025-26/770 , 26-SEP-2025
3. Number of Sample : LS/RL/HZ/2025-09/001
4. Date of receipt : 26-SEP-2025
5. Names of drugs purporting to be contained in the sample : Paracetamol Tablets IP 500 mg,

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSGSD/HYD/2025-26/0043	HYD/LSGS/2025-26/42	BTH-19	01-Feb-2025 31-Jan-2027	NA	Bengal Chemicals And Pharmaceuticals, E-35 Industrial Area Haridwar-249401 UK

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

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

Date of Testing : From 27-Oct-2025 To 29-Oct-2025

COMPOSITION : Each uncoated tablet contains: Paracetamol IP 500 mg

**Protocol Applied : I.P. 2022**

Sr No.	Test Name	Result	Limits
1	Description	White, circular, flat, bevelled, uncoated tablets, scored on one side, packed in aluminium blister strip, enclosed in paper carton box.	NA
2	Identification	Positive for Paracetamol	NA
3	Average weight	631.04 mg	NA
4	Uniformity of weight	Complies	NA
5	Test for Dissolution-Paracetamol-S1 level (6 Units)	38.41 %, 39.47 %, 43.74 %, 42.94 %, 47.74 %, 45.07 % of Claim (Out of 6 units, all units found less than 85 % of Claim (80 + 5 % i.e Q + 5 %))	NLT 80 % of Claim



6	Test for Dissolution-Paracetamol-S2 level (6 Units)	45.65 %, 37.61 %, 39.05 %, 38.47 %, 42.78 %, 41.34 % of Claim (Average of 12 units (S1+S2) is 41.86 % of Claim. Out of 12 units, all units found less than 80 % of Claim and 65 % of Claim (80-15 % i.e. Q-15 %))	NLT 80 % of Claim
7	Test for Dissolution-Paracetamol-S3 level (12 Units)	44.17 %, 39.41 %, 34.66 %, 33.26 %, 38.02 %, 45.56 %, 35.78 %, 42.49 %, 40.53 %, 37.18 %, 30.75 %, 46.96 % of Claim (Average of 24 units (S1+S2+S3) is 40.46 % of Claim. Out of 24 units, all units found less than 80 % of Claim, 65 % of Claim (80-15 % i.e. Q-15 %) and 55 % of Claim (80-25 % i.e. Q-25 %))	NLT 80 % of Claim
8	Test for Dissolution Results for S1, S2 and S3 Levels-Paracetamol (24 Units)	Average of 24 units (S1+S2+S3) is 40.46 % of Claim. Out of 24 units, all units found less than 80 % of Claim, 65 % of Claim (80-15 % i.e. Q-15 %) and 55 % of Claim (80-25 % i.e. Q-25 %)	NLT 80 % of Claim
9	Related substances	Complies	NA

### Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Paracetamol	487.897 mg	500 mg	97.579	95 % to 105 %	I.P. 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 there under for the reasons given below:-

**THE SAMPLE RECEIVED DOES NOT CONFORM TO I.P. 2022 SPECIFICATION WITH RESPECT TO THE TEST FOR DISSOLUTION ONLY.**

CDTLH REPORT NO.: CDTLH/0760/F-0457/2025-26

Date: 30-OCT-2025



GOVERNMENT ANALYST

डॉ. ए. रघुराम रेड्डी / Dr. A. Raghuram Reddy, M.Pharm, Ph.D.  
 सरकारी विद्वान / Government Analyst  
 केंद्रीय औषधि परीक्षण प्रयोगशाला / Central Drugs Testing Laboratory  
 केंद्रीय औषधि मानक नियंत्रण संगठन / Central Drugs Standard Control Organisation  
 स्वास्थ्य सेवा महानिदेशालय / Directorate General of Health Services  
 स्वास्थ्य एवं परिवार कल्याण विभाग / Ministry of Health & Family Welfare  
 भारत सरकार, Government of India  
 एम.आर.नगर, हैदराबाद-500032 / S.R. Nagar, Hyderabad - 500 032

Report in the red colored paper indicates the sample is not of standard quality

END OF REPORT