

GOVERNMENT OF ANDHRA PRADESH  
DRUGS CONTROL ADMINISTRATION

**From**

M B R Prasad, M.Pharm, M.Phil, A.I.C  
Director & Licensing Authority,  
O/o.The Director General,  
Drugs Control Administration,  
Chuttugunta,  
Guntur-522 004.  
Andhra Pradesh, India.

**To**

M/s. Synergene Active Ingredients Private Limited,  
Unit-III, Plot No.59-A,  
J.N. Pharma City,  
Parawada (Village & Mandal)  
Visakhapatnam District-531 021,  
Andhra Pradesh, India.

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made there under – Issue of  
**World Health Organization G.M.P. Certificate** – Regarding

Ref: 1. Your Application dated: 29-12-2021.  
2. Joint Inspection dated: 16-02-2022 to 18.02.2022.  
3. Ref: 5-6(215)2022/2240, dated:29.08.2022 of Dy. Drugs Controller (I),  
CDSCO, Hyderabad.

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I, forward here with **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE Certificate** for the products mention in the Joint Inspection Report of the Officers of Drugs Control Administration, Andhra Pradesh and CDSCO, Hyderabad.

**This certificate is valid up to 09.05.2025 and this certificate is meant for export of drugs only.**

**Yours faithfully**



Digitally signed by BABU  
RAJENDRA PRASAD MEESALA  
Date: 2022.09.30 18:35:09  
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**DIRECTOR & LICENCING AUTHORITY  
DRUGS CONTROL ADMINISTTATION**

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DRUGS CONTROL ADMINISTRATION

Office of the Director,  
Licensing & Approving Authority  
Drugs Control Administration,  
Chuttugunta, Guntur-522 004.  
Andhra Pradesh, India.

LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATION SCHEME  
FOR EXPORT PURPOSE

**FEXOFENADINE HYDROCHLORIDE BP/Ph.Eur/IP/USP.**

**Manufacturer** : M/s. Synergene Active Ingredients Private Limited,  
Unit-III, Plot No.59-A,  
J. N. Pharma City,  
Parawada (Village & Mandal),  
Visakhapatnam District-531 021,  
Andhra Pradesh, India.

**Drug Licence No.** : 28/VSP/AP/2021/B/G, dated 01-06-2021  
Valid up to 31.05.2026 in Form-25

It is also certified that

- a) The manufacturing plant in which the products are produced is subject to inspection at suitable intervals.

The unit M/s. Synergene Active Ingredients Private Limited, Unit-III, Plot No.59-A, J.N. Pharma City, Parawada (Village & Mandal), Visakhapatnam District- 531 021, Andhra Pradesh, India was jointly inspected by Sri. N. Yugandhar Rao, Drugs Inspector, Narsipatnam, Drugs Control Administration, and Sri. R.Srinivasan, Asst.Drugs Controller (I), CDSCO , Visakhapatnam on dated: 16.02.2022 to 18.02.2022.

- b) The Manufacturer confirm to requirement for Good Manufacturing Practices in the manufacture and quality (As recommended by the World Health Organisation) in respect of products mentioned above (One Number) for Export in the International Market.

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Parawada (Village & Mandal), Visakhapatnam District-531 21,  
Andhra Pradesh, India.