

**WITHDRAW - NOTICE OF CONCERN  
ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD.  
A-31 CLINICAL SITE, MIDC, TTC INDUSTRIAL AREA  
KHAIRANE, NAVI MUMBAI  
400709, MAHARASHTRA, INDIA**

The WHO Prequalification Unit (WHO-PQT) would like to inform Drugs Controller General of India (DCGI) and, national regulatory Authorities, procurement agencies and other stakeholders that the Notice of Concern (NOC), issued 9 November 2022 to Accutest Research Laboratories (I) Pvt. Ltd., the Clinical Unit of Unit I located at A-31, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai, 400709, Maharashtra, India by WHO-PQT, has been withdrawn, removed from the WHO Prequalification Unit website and archived.

The NOC was originally issued after an inspection performed on 30 May – 3 June 2022, during which several critical and major non-conformities were identified. In response, WHO-PQT requested the applicants of the affected products to thoroughly review the impact of these findings and take appropriate actions to ensure their compliance with WHO GCP/GLP/BE guidelines.

The review process has been successfully concluded, encompassing data and reports derived from recent studies conducted by the CRO. Notably, the studies include ARL/22/087 for CV 020: Ritonavir 100 mg + Nirmatrelvir 300 mg Film-coated tablets and ARL/20/027 for MA193: Sulfadoxine 500 mg and Pyrimethamine 25 mg Tablets. These submissions have been evaluated and have been determined to adhere to the mandated standards of WHO GCP/GLP/BE guidelines. The assessment of data from these studies supports the new products, effectively addressing concerns that had previously been raised in the Notice of Concern.

For further information please visit the WHO Prequalification Unit website at <https://extranet.who.int/pqweb> or contact PQT directly at [prequal@who.int](mailto:prequal@who.int)

With best regards

***WHO Prequalification Unit (PQT)***

World Health Organization

Geneva, Switzerland

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