the design of the room including presence of a workbench, availability of chemicals, power sockets and presence of various unexplained analytical reports and different study related documents including service records of an out-of-use equipment (ABX Micros 60 haemolyzer), it cannot be excluded that the room was not used for other purposes.

3. A lack of laboratory oversight by the quality control unit in that a Horiba haematology analyser model "ABX Micros 60" was not reflected on the pathology laboratory's list of equipment since 2019; however, an unjustified service report dated March and November 2019 for the haemolyzer ABX Micros 60 was picked up from the hidden room.
4. Incomplete datasets without dynamic record formats as vast amounts of study-related documentation and chemicals, also associated with applications submitted to the other authorities, were identified in the hidden room which indicate lack of oversight and inadequate retention of study data.
5. Inadequate computer access control which led to data being deleted and manipulated without a clear trail of staff interacting with the data.
6. Compromising of current Attributable, Legible, Contemporaneous, Original and Accurate (ALCOA+) principles due to failure in providing a complaint LIMS software system to ensure that data was stored and transferred correctly, and a non-editable audit trail report was generated and reviewed.
7. Inadequate recording of sample re-analysis at the pathology laboratory resulted in an inability to report adequately to the sponsor and allow for an informed decision on the proper handling of adverse events and treatment of subjects.
8. Lack of adequate quality management and the associated risk-based approach resulted in the absence of an audit trail review with proper frequency to prevent any data modification/deletion, process improvement, or identification of deficiencies.
9. Inadequate separation of duties between the system administrator (using vendor credentials) and the pathology laboratory staff, leading to staff with a direct interest in the data to modify and delete data.

Seeing that the nature of the observations was such that retrospective corrective action was not considered to be possible for the three studies under review affecting the three product applications, i.e. HA715, MA155 and MA165, WHO-PQT will request the applicants of the affected product applications to review the impact of these findings and take actions to confirm bioequivalence and safety of their products. Until such time as the required confirmation has been received and assessed by WHO-PQT, the applications HA715, MA155 and MA165 will be suspended.

Kindly be advised that further corrective actions would be required by Accutest Research Laboratories (I) Pvt. Ltd **A-31 Clinical Unit** only for the purposes of removing the NOC from the WHO website, and/or only if:

- the sponsors, i.e., Lupin Ltd. and Guilin Pharmaceutical Co Ltd expressed the intention of submitting another study performed by your site (Unit I, A-31) to the WHO Prequalification Unit.
- another sponsor, in the future, submitted a study from Accutest Research Laboratories (I) Pvt. Ltd. in a dossier that was accepted for assessment

and an inspection confirms the compliance of the site with current Good Clinical Practice Standard.

Further to the above, please be advised that this NOC does not affect any of the Applications submitted to WHO for purposes of prequalification where the studies were conducted at the Accutest Research Laboratories (I) Pvt. Ltd **A-31 Bio-analytical Unit.**

For further information please visit the WHO Prequalification Team - Medicines (PQT/MED) website at https://extranet.who.int/pqweb/ or contact PQT directly at prequal@who.int.

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