



F. No. 03-21/2020- DRAP
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination
Division of Pharmacy Services
>>>><<<<

Islamabad, 13th April, 2020

✓ Professor Javed Akram
Vice Chancellor
University of Health Sciences
Lahore.

"SAY NO TO CORRUPTION"

Sub: **APPLICATION FOR REGISTRATION OF PROTECTS CLINICAL TRIAL ENTITLED "HYDROXYCHLOROQUINE, OSELTAMIVIR AND AZITHROMYCIN FOR THE TREATMENT OF COVID-19."**

I am directed to refer to your application dated 1st April on the subject cited and to state that your case was discussed in the 9th meeting of Clinical Study Committee, held online through on 8th April, 2020. The CSC decided as under:

Decision of 9th CSC meeting:

It was the same case as was presented in 8th meeting of CSC held online. The CSC after detailed deliberation and owing to situation of COVID-19 pandemic in Pakistan, decided to approve the Protects clinical trial entitled "Hydroxychloroquine, Osetamivir and Azithromycin for the treatment of COVID-19". However, the CSC also directed the applicant to fulfil the shortcomings within one week; otherwise the study would stand deferred

2. Refer to the aforementioned decision, you are advised to remove the following shortcoming within weeks as decided by CSC:
- Application is not on prescribed Form-II of the Bio-Study Rules 2017.
 - Quantity of drug / trial material to be imported or used in the trial is not described.
 - Investigator Brochure is not provided.
 - None of the described clinical trial sites is approved from DRAP. The applicant has neither submitted applications on Form I, nor has submitted fee for the licensing of each clinical trial site. The applicant should be asked to submit separate application along with fee for all the four trial sites.
 - Institutional Review Board (IRB) approval of sites with complete composition of committee is not provided, only consideration letter from Dr. Nadeem Afzal, Convener, Ethical Review Committee, and University of Health Sciences Lahore has been attached.
 - Approval from NBC is not attached.
 - GMP certificate along with COPP & free sale certificate are not provided.
 - Pre-clinical/clinical safety studies are not provided.

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29-4-2020

Dr. M. Shafiqul

- ix. Summary of Investigator Brochure is not provided.
- x. Evidence of registration in country of origin is not provided.
- xi. Sample of label of the investigational product / drug is not provided.
- xii. Undertaking on stamp paper is not provided.

3. Necessary response on the matter should be provided at the earliest.

AM Mateen
13.04.2020

Abdul Mateen
Assistant Director,
Division of Pharmacy Services

Copy to:

- 1- Director, Division of Pharmacy Services.
- 2- Office Copy.