Schedule-13
(Relating to Sub-rule (2) of Rule 8)
Government of Nepal
Ministry of Health and Population
Department of Drug Administration

Ref. No. 2424

License for clinical trial

This license is hereby issued, setting out the following matters, allowing the following person to conduct clinical trial of the following new drug, subject to the Drugs Act, 2035(1978) and the Drugs Registration Rules, 2038(1981).

1. Of the new drug licensed for clinical trial:

Name	System	Group or Subgroup	Composition	Type or Kind	Active ingredient's		Remarks
					Name	Quantity	
ASPIRIN	ALLOPATHY	KHA	ASPIRIN	TABLET	ASPIRIN	150MG/TAB	
COLCHICINE	ALLOPATHY	KHA	COLCHICINE	TABLET	COLCHICINE	1MG/0.5MG/TAB	
TOCILIZUMAB	ALLOPATHY	KHA	TOCILIZUMAB	INJECTION	TOCILIZUMAB	400MG/20ML	

2. Of the disease licensed for clinical trial:

(a) Name: COVID -19

(b) Method of diagnosis: Clinical symptoms as well as laboratory diagnosis with real time PCR testing

3. of the consumption of the new drug to be administered in the course of clinical trial:

(a) Method: Oral form and COLCHICINE for ASPIRIN and Intravenous Infusion for TOCILIZUMAB (b) Mode: Tocilizumab will be given as a single intravenous infusion over 60 minutes in 100ml sodium chloride 0.9%. A second dose may be given ≥12 and <24 hours later if, in the opinion of the attending clinician, the patient's condition has not improved.

(b) Dosage (daily):

ASPIRIN: 150 mg by mouth (or nasogastric tube) or per rectum once daily until discharge.
COLCHICINE : 1 mg stat dose then 500mcg after 12 hours and continue 500 mcg every 12 hours for 10 days
TOCILIZUMAB : Single dose: 8 mg/kg (max 800 mg)
A second dose may be given ≥12 and 24 hours later if, in the opinion of the attending clinicians, the patient's condition has not improved.

(c) Period: Aforementioned for specific interventions

4. Mode of clinical trial: Open Label Randomised Controlled Trial, Adaptive

5. Place where clinical trial is to be conducted:

BP Name and address of hospital: Teku Hospital (Shukra raaj Tropical & Infectious Disease Hospital) and Armed Police Force Hospital

Name and address of other doctor: As assigned by the study sites and orientation provided by NHRC

6. Of the person allowed conducting clinical trial:

(a) Name, surname and address: DR PRADIP GYANWALI (NMC NO 5725)/ DR BUDDHA BASNYAT (NMC NO: 1290)

(b) Occupation: MD CLINICAL PHARMACOLOGIST/ MD INTERNAL MEDICINE

(c) Qualifications: MBBS, MD

7. Validity period of license: 2 YEARS FROM DATE OF ISSUE.

License receiver's: DR. SUMAN PANT (NMC NO: 12983)

Signature:

Date:

License issuing officer's:

Signature:.....

Name: SANTOSH KC

Date: 2077/10/26

Designation: SENIOR DRUG ADMINISTRATOR

Senior Drug Administrator
Ten Level