## GOVERNMENT OF PAKISTAN Ministry of National Health Services, Regulations & Coordination Drug Regulatory Authority of Pakistan T.F. Complex. Sector G-9/4, Islamabad

Islamabad, the 6<sup>th</sup> April. 2020

## **NOTIFICATION**

**F.No.4-2/2017-DD (H&OTC) (Pt.).** In exercise of the powers conferred by section 7(c) (ix) of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with rule 3(2)(d) of the Alternative Medicines and Health Products (Enlistment) Rules, 2014, the Drug Regulatory Authority of Pakistan considering the public health urgency and the dire need of availability of quality hand sanitizers during COVID-19 pandemic, decided the following in the best public interest:-

(I) The manufacturers having valid Drug Manufacturing License (DML) or valid Enlistment Certificates (Form-6) with topical or external preparations section may prepare hand-sanitizer with the below mentioned WHO recommended formulations only on campaign basis for a period of three months with the provisional permission of the Health & OTC Division:

- a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution denatured; OR Isopropyl Alcohol (75%, v/v) in an aqueous solution.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).

(II) The applicant may apply to the Health & OTC Division along with fee of Rs.5000/under miscellaneous heading.

(III) This provisional permission for campaign manufacturing will expire on 02.07.2020.

(MUHAMMAD ABDUL GHAFFAR) Additional Director, Division of Health & OTC Products