

Dated: <u>03-05-2021</u>

No.F.10-3/2021-DD (H&OTC) (M-87) DIVISION OF HEALTH & OTC PRODUCTS DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-6 [(See rule 7(16)]

PROVISIONAL CERTIFICATE FOR ENLISTMENT AS MANUFACTURER

E. No. 01189 Dated: 03-05-2021

M/s Selco Research Laboratories, located at the address, Plot No 50/3-A, Phase – 1 & 2, Industrial Estate, Hattar, Khyber Pakhtunkhwa, is hereby enlisted in the enlistment register as manufacturer [Tablet Section (Nutraceutical), Capsule Section (Nutraceutical), Oral Powder (Sachet) Section (Nutraceutical), Oral Liquid Section (Nutraceutical), Cream/Ointment Section (Nutraceutical)], by the Authority [approved in 87th Meeting of EEC held on 24th March, 2021 vide F.No.1-74/2020-(H&OTC)], subject to the following conditions namely:-

- a. The manufacturer shall be responsible for the quality, efficacy and safety of all the therapeutic goods manufactured and sold by him.
- b. He shall abide by all the provisions of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) except those exempted under the said Act.
- c. He shall immediately recall the defected therapeutic goods within 15 days after intimation to him and report the compliance to the Authority.
- d. He shall be responsible to withdraw the unsafe therapeutic goods from the market if so declared by the Authority. He shall also report adverse affect reports, (if any), to the Authority within 15 days period and notify focal person for such reporting.
- e. Any other relevant condition imposed by the Authority in future.
- f. This certificate shall not be valid after the date notified by the Authority through official gazette.
- g. Certificate of enlistment shall be surrendered to the Authority within 7 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

Secretary, Enlistment Evaluation Committee
Division of Health and OTC,

Drug Regulatory Authority of Pakistan