Instruction No. 107

File No: K-43022/67/2020-SEZ-Part(1)
Government of India
Ministry of Commerce & Industry
Department of Commerce
SEZ Division

Udyog Bhavan, New Delhi
Dated the 26th August, 2021

To,

All Development Commissioners Special Economic Zones

Subiect: Request for feedback-
Minimising Regulatory Compliances in respect of Pharma Industry-reg.

Sir(s),

I am directed to say that this Department has received a proposal from M/S Biocon through Department of Pharmaceuticals to reduce the regulatory compliance in respect of Temporary removal of challan procedure in SEZ. M/S Biocon has represented that as per Rule 50(3) of SEZ Rules, 2006, a unit may transfer goods for quality testing or research and development purposes, to any recognized laboratory or institution without payment of duty, on giving an undertaking to the authorized officer for the return of such goods. At the time of transfer of such goods the authorities ask for the recognition certificate of the firm where the goods are sent. The matter has been examined in the Department.

2. Development Commissioners are requested that any laboratory or institution which have been accredited for Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) may be accepted as recognized laboratory or institution for quality testing or research and development under Rule 50(3) and their certificate may be accepted as required in Proviso to Rule 50(3) of SEZ Rules, 2006.
3. This issues with the approval of competent authority.

Yours faithfully,

(Ashish Prakash Sinha)
Under Secretary to the Govt. of India
Tel. 23062496
e-mail: ashishprakash.sinha@nic.in

Copy to: Shri Pawan Kumar, Joint Director, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Shastri Bhawan, New Delhi.