Your Ref.:

Our Ref.:

(7) dlm.BPFK/30/12/2200

Date:

10 December 2020

Managing Director Medispec (M) Sdn. Bhd. 55 & 57, Lorong & Sempadan 2 11400 Ayer Itam Penang

(Attn.: Ms. Lim Choon Moi)

Dear Madam,

RESULT OF GOOD MANUFACTURING PRACTICE (GMP) DESKTOP ASSESSMENT FOR FOREIGN GMP INSPECTION FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS WITH THE DRUG CONTROL AUTHORITY (DCA)

NAME & ADDRESS

GETZ PHARMA (PVT) LTD.,

MANUFACTURER

PLOT 29-30, SECTOR 27, KORANGI

INDUSTRIAL AREA, 74900 KARACHI,

PAKISTAN.

PRODUCT CATEGORY

NON-STERILE

Thank you for your application for the Foreign GMP Inspection that was received by the Centre of Compliance and Quality Control (CCQC), National Pharmaceutical Regulatory Agency (NPRA) on 01 June 2020.

- 2. We are pleased to inform that the application has been reviewed and the GMP evidence provided was found to be acceptable. Therefore, the manufacturer's GMP compliance status will be extended until **04 April 2023**.
- 3. Please take note that this extension of GMP compliance status is only for the purpose of retention of product registration status/new registration/renewal of product registration with the DCA. Should you have any further queries, please contact Ms Meera Kumari D/O Ram Navas at (03-78835508/meera@npra.gov.my).

MEERA KUMARI RAM NAVAS (RPh 10963) Ketua Penolong Pengarah Pusat Komplians & Kawalan Kualiti

Pusat Komplians & Kawalan Kualiti Bahagian Regulatori Farmasi Negara Kementerian Kesihatan Malaysia

Our Ref.: (7) dlm.BPFK/30/12/2200

Your co-operation and attention in this matter is highly appreciated.

Thank you.

"SERVE THE NATION"

Yours faithfully,

-sign-

(DR. ROSHAYATI MOHAMAD SANI) RPh. 1449

Deputy Director Centre of Compliance and Quality Control National Pharmaceutical Regulatory Agency Ministry of Health of Malaysia

RMS/meera

cc Deputy Director
Centre of Product and Cosmetic Evaluation
National Pharmaceutical Regulatory Agency

CERTIFIED TRUE COPY

MEERA KUMÁRI RAM NAVAS (RPh 10963)

Ketua Penolong Pengarah Pusat Komplians & Kawalan Kualiti Bahagian Regulatori Farmasi Negara Kementerian Kesihatan Malaysia