



# KEMENTERIAN KESIHATAN MALAYSIA

(Ministry of Health Malaysia)

## Bahagian Regulatori Farmasi Negara (NPRA)

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Our Ref: (15) dlm.BPFK/30/12/2200 Bng 3  
Date : 2 August 2023

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

(Attn. Ms. Lim Choon Moi)

Ms.,

### THE APPLICATION FOR FOREIGN GOOD MANUFACTURING PRACTICE (GMP) INSPECTION FOR THE REGISTRATION OF PHARMACEUTICAL PRODUCTS WITH DRUG CONTROL AUTHORITY (DCA), MALAYSIA

NAME	: GETZ PHARMA (PVT.) LTD.
MANUFACTURE'S ADDRESS	: PLOT 29-30, SECTOR 27, KORANGI INDUSTRIAL AREA, 74900 KARACHI, PAKISTAN
PRODUCT CATEGORY	: NON-STERILE

We refer to the above matter and your application for the Foreign Good Manufacturing Practice Inspection received by the Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency (NPRA) on 05 December 2022.

2. We have reviewed and assessed the application through the GMP Desktop Assessment (GDA) platform. The assessment found that the manufacturer has an acceptable level of GMP compliance and therefore, its GMP status will be **extended to 04 April 2025**. The validity period of extension is granted due to the GMP proof of authentication status that has been issued by NPRA as follows:

- 2.1 GMP field inspection that was carried out by the NPRA on 02-05 April 2018.
- 2.2 GMP Certificate (Reference No.: M040/18; Validity Period; 05 April 2021) issued by NPRA for the said manufacturer.
- 2.3 First GDA extension granted (Ref No: (7) dlm.BPFK/30/12/2200 ; Validity Period: 04 April 2023).

3 Please be reminded that this extension is only for the purpose of sustaining the registration status / new product registration / re-registration of a product registered under the Drug Control Authority (DCA). Any further inquiries, please contact **Ms. Cheok Xin Yin** (03-78835499/ [cheok@npra.gov.my](mailto:cheok@npra.gov.my)) or **Mr. Muhammad Amirul Naqiuddin bin M Azmi** (03-78835400 ext. 4234 / [amirul.n@npra.gov.my](mailto:amirul.n@npra.gov.my)).

Your cooperation and attention in this matter are greatly appreciated.

Thank you.

**"MALAYSIA MADANI"**

**"BERKHIDMAT UNTUK NEGARA"**

Yours faithfully,



**(DR. NORAI DA MOHAMAD ZAINOOR)** RPh. 2289

Deputy Director

Centre of Compliance & Quality Control

National Pharmaceutical Regulatory Agency

Ministry of Health Malaysia

MNMN/cxy/amirul

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c.c. Deputy Director  
Centre of Product & Cosmetic Evaluation  
National Pharmaceutical Regulatory Agency  
(Attn. Head of Generic Section)