DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Dr, Rm 2037 HFC-130 Rockville, MD 20857 FDA483responseinternational@fda.hhs.gov	3/3/2026-3/6/2026* FEI NUMBER 3006649152

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Key Kar Wai, Factory Director

FIRM NAME	STREET ADDRESS
Dxn Pharmaceutical Sdn Bhd	KG. Padang Panjang, Jalan Bukit Wang
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jitra, Kedah, 06000 Malaysia	Dietary Supplement Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Your master manufacturing record did not include all required information.

Specifically, during the inspection on 3/3/2026, it was determined that your master manufacturing records did not include a complete description of packaging materials used in the manufacture of your dietary supplement products.
For example:

- **RG Capsule 270mg:** The Master Manufacturing Record includes a packaging materials section that lists the (b) (4) bottle, but does not include (b) (4) desiccant packets. During the inspection, I observed your production employees adding (b) (4) packets to bottles during the packaging operation. Your production employee stated that (b) (4) packets are added to all capsule and tablet products.
- **Potenzhi Capsule:** The Master Manufacturing Record dated (b) (4) includes a packaging materials section that lists the (b) (4) bottle, but does not include (b) (4) desiccant packets.

Without a complete description of all packaging materials in the master manufacturing record, including (b) (4) desiccant packets, you cannot ensure the consistent packaging of your finished dietary supplement products from batch to batch.

***DATES OF INSPECTION**
3/03/2026(Tue), 3/04/2026(Wed), 3/06/2026(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jackson Y See, Investigator X Jackson Y See Investigator Signed By: 2002562116 Date Signed: 03-06-2026 10:36:11	3/6/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."