

Date:2080-02-16

Dietary Supplement Product Registration Certificate

Please refer to your Application 4356789 regarding grant of dietary supplement product registration under Dietary Supplement Regulation Guidelines 2072. The product registration certificate for the above mentioned application is granted as per the details given below. Detail of label is attached in Annexure I.

<u>Registration Number</u>	<u>Name of Product</u>	<u>Date of approval</u>	<u>Validity</u>
01777800220	Fatozyme Tab	2080-02-12	2080-02-09

Details

Active ingredients:/tablets	Foenicullum Vulgare(Fennel oil)-10mg; Anethum graveolens(Dill oil)-10mg; Pimpinella anisum(Aniseed Oil)-10mg; Mentha Piperata(Pippermint Oil)-10mg; Diastage-50mg Pepsin-10mg; Bacillus coagulans-1 billion cfu.		
Product Type	Nutraceuticals	Size of pack	10x1x10 Tablet
Form of Product	Tablet		
Dose specified	one tablet two times a day after meal or as directed by specialist		
Health claim	Not Allowed	Nutritional claim	Not Verified
Expiry period claim	best before 24 months from date of MFD		
Name of Manufacture	Asta Organics, Sonipat, Haryana		
Country	India		
Manufacturing Lic No.	10018064001403		

Terms and Condition

1. This certificate is applicable for the purpose of obtaining permission from the Department for the purpose of import, sale or distribution of dietary supplement and the application for the renewal must be made not later than 30 days of expiry.
2. Prior approval has to be obtained from the Department if any alteration is to be made in the product specification and label submitted to the department in the above mentioned details.
3. Prior to the import, concerned party has to obtain import permit for the registered products from the Department.
4. The registration of the product is effectively within the domain of Food Act, 2023, Regulation, 2027 and Dietary Supplement Regulation Guidelines, 2072. It is the responsibility of the party to respond to the concerned act and regulation of Nepal whenever necessary.
5. Please note that your application had been considered on the basis of the documents submitted. The firm will be responsible for the authenticity of the documents supplied while obtaining registration certificate.



Yours Faithfully

(As per section 2, subsection 13 of the Dietary Supplement Regulation Guidelines, 2072)