



Section A: General Information:

1. Submission type:

Foreign Local

2. Manufacturing type:

Complete Manufacturing Contract Manufacturing Toll manufacturing

clarify.....

3. Type of product

3.1. Dietary Supplement & Health Product

Dietary Supplement Health Product

4. Product Identification:

4.1. Trade name : Infa D3

5. Manufacturer:

5.1. Name: Elegant India

5.2. Address: 205, Kirtiman , Opp .Kadva Patidar Hostel , Off C.G. Road , Navrangpura, Ahmedabad - India

5.3. E-mail: elegant @adl.vsnl.net

6. Marketing Authorization Holder:

6.1. Name: Elegant India

6.2 Address: 205, Kirtiman , Opp .Kadva Patidar Hostel , Off C.G. Road , Navrangpura, Ahmedabad - India

6.3. E-mail: elegant @adl.vsnl.net

7. Registration Status of the product in exporting country:

The product is registered and marketed in the exporting country:

The product is registered but not in the market in the exporting country, explain?

The explanation by documents

.....
.....

The product is not registered in the exporting country, explain?

The explanation by documents.

8. Registration in other countries:

List the countries where the product is registered:

India, Pakistan , Egypt

Section D: (Dietary Supplement & health product)

1. Generic name: Vitamin D3*
2. Source of product: Vitamin
3. Indented use: For deficiency of vitamin D3
4. Dosage form: Drops
5. Pack size: 20 ml
6. Full description of primary and secondary package: Amber round pet bottle contains 20 ml of light yellow color solution for oral drops, packed along with dropper in a carton box.
7. Route of administration: Oral
8. Storage condition: Store below 25 °C in a cool & dry place. Protect from direct sunlight.
9. Shelf life: 36 month
10. Composition formula:-

Name of ingredient	Function	Concentration	Unit
Cholecaliferol USP	Active ingredient	25	µg
Sorbitol	Excipient	5	mg

Note:

- ❖ In case of the space of generic name is not enough to write the full name of each ingredient, you can write the generic like this: Vitamin (A, C, B1, B2, B3, and B6). Minerals (K, Na, Ca, Si, Cu.....etc.)For herbal ingredients it should be written as it.

Commitment

I, the undersigned,

..... (Name and position in the company, e.g. General Manager, Authorized Person,) (Name of the company), certify that the information provided (above) is correct and true and the product submitted for registration is safe and does not contain any harmful or prohibited material.

(For foreign products):

(If the product is marketed in the country of origin, tick the following boxes as applicable):

And I declare that the product submitted for registration is identical in all aspects of manufacturing and quality to the marked in:(country of origin), including formulation, method and site of manufacture, sources of active ingredients and excipient starting materials, quality control of the product and starting materials, packaging, shelf-life and product information;

And I declare that the product submitted for registration is identical to that marketed in: (Country of origin), except for

(e.g. formulation, method and site of manufacture, sources of active ingredients and excipient starting materials, quality control of the finished product and starting materials, packaging, shelf-life, indications, and product information)

Date: 23/7/2020

Signature: xxxx