

1. Licence/Permit/Certificate/Listing/Notification/Registration Summary

1.1

Therapeutic Products – Product Registration

Licence/Permit/Certificate/Listing/Notification/Registration

Type :

1.2

SIN13048P

Licence/Permit/Certificate/Listing/Notification/Registration

No :

1.3 Company Name :

VIATRIS PRIVATE LIMITED

1.4 Approved Date :

17/02/2005

1.5 Expiry Date/ Retention Fee Payment Due Date :

16/02/2023

2. Product Particulars

2.1 Product Name :   INSPRA TABLETS 25mg (TABLET, COATED )

Active Substances

2.2 Name

Strength

EPLERENONE           25 mg

Packaging

2.3 Container Closure System (CCS)

Quantity per CCS

CCS per Pack

Shelf Life

Cold Chain

Storage Condition

Opaque PVC–Alu Blister

10 tablets/blister

3

36 (Months )

N

Store at or below 30°C

Opaque PVC–Alu Blister

10 tablets/blister

5

36 (Months )

N

Store at or below 30°C

2.4 Company Address

1, GATEWAY DRIVE #14–08/16 SINGAPORE 608531

:

2.5 Forensic classification :

– Prescription Only

ATC

2.6 ATC Codes

NIL

Manufacturers

2.7 Manufacturer Name

Manufacturer Type

Manufacturer Operation

Country of Manufacturer

Pharmacia & Upjohn Company LLC

Active Substance Manufacturer

UNITED STATES

Excella GmbH (milling)

Active Substance Manufacturer

GERMANY

Fareva Amboise

Finished Product Manufacturer (Overseas)

Packing / Labelling

FRANCE

ZUELLIG PHARMA SPECIALTY SOLUTIONS GROUP PTE. LTD.

Finished Product Manufacturer (Local)

Labelling

SINGAPORE

Pfizer Pharmaceuticals LLC – Vega Baja

Finished Product Manufacturer (Overseas)

Bulk Production

PUERTO RICO

2.8 Site for Batch Realease

Name of Batch Realease

Country of Manufacturer

Name of Manufacturer

Fareva Amboise

FRANCE

All registrants under the Health Products Act (HPA) must comply with the HPA and its regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Registrants must also comply with all other applicable laws and their regulations.

3. The Licence/Permit/Certificate/Listing/Notification/Registration is issued subject to the following conditions

NA.

#### 4. List of Attachments

Doc Type: Part 1 – 1.4.2 Inner/Blister Labels

| S/No. | Doc Name                                                       | Approved Date |
|-------|----------------------------------------------------------------|---------------|
| 1     | <a href="#">1.4.2 Blister Label_imme label_Inspra 25mg.pdf</a> | 19-Mar-2012   |

Doc Type: Part 1 – 1.4.1 Outer/Carton Labels

| S/No. | Doc Name                                                                                  | Approved Date |
|-------|-------------------------------------------------------------------------------------------|---------------|
| 1     | <a href="#">1.4.1f Inspra 25mg_50s Outer Carton [SG-NM].[MY-NM] OFG-3 Pristine.pdf</a>    | 01-Jul-2021   |
| 2     | <a href="#">1.4.1c Inspra 25mg_30s Outer Carton [SG-NM].[MY-M] EC8438514 Pristine.pdf</a> | 01-Jul-2021   |

Doc Type: Part 1 – 1.4.3 Package Insert (PI)

| S/No. | Doc Name                               | Approved Date |
|-------|----------------------------------------|---------------|
| 1     | <a href="#">INSPIRA TABLETS PI.pdf</a> | 01-Jul-2021   |

The above information is current as of the date of print: 24/05/2022



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