

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

1.1

Therapeutic Products – Product Registration

Licence/Permit/Certificate/Listing/Notification/Registration

Type :

1.2

SIN13049P

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 50mg (TABLET, COATED)

Active Substances

2.2 Name

Strength

EPLERENONE

50 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

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

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	1.4.2 Blister Label_EC8309480-INSpra_50mg.pdf	20-Mar-2012

Doc Type: Part 1 – 1.4.1 Outer/Carton Labels

S/No.	Doc Name	Approved Date
1	1.4.1f Inspra 50mg 50s Outer Carton [SG-NM].[MY-NM].OFG-3 Pristine.pdf	01-Jul-2021
2	1.4.1c Inspra 50mg 30s Outer Carton [SG-M].[MY-M].EC8434803 Pristine.pdf	01-Jul-2021

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

S/No.	Doc Name	Approved Date
1	INSpra TABLETS PI.pdf	01-Jul-2021

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



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Last Updated 16 Oct 2019