



Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name of site: M/s. Lee Pharma Limited.
2. Manufacturer's Licence Number : 33/NP/AP/2010/F/R dated 15.07.2010

The address of manufacturer and name of product mentioned in annexure -1 of the Written Confirmation Certificate (WC-0421) granted on date 22.03.2018 is hereby amended as follows:

In place of:

"M/s. Lee Pharma Limited, Plot No. V, Phase -II, VSEZ, Duvvada, Sabbavaram (M), Andhra Pradesh, India."

And

"Esomeprazole Magnesium Dihydrate Pellets 22.0 w/w
Each 1 gram of Enteric coated Pellets contain:
Esomeprazole Magnesium Dihydrate IHS
Equivalent to Esomeprazole 222.0mg."

Read as:

"M/s. Lee Pharma Limited, Plot No: V, Phase -II, VSEZ, Duvvada, Sabbavaram (M), Visakhapatnam District-530049, Andhra Pradesh, India."

And

"Esomeprazole Magnesium Dihydrate Pellets 22.0 % w/w
Each 1 gm of Enteric coated pellets contain:
Esomeprazole Magnesium Dihydrate IHS
Equivalent to Esomeprazole 220.0mg."

All the other conditions of Written Confirmation Certificate will remain same.


Signature


Stamp of the authority and date

14 MAY 2018