



Date: 25-Mar-2022

Ref: SR/2022/0003

To: Ipca Laboratories Limited

street/plot number: Mum1256

region/state: Indi

countryss: India

Subject: Queries to Applicant - for the Registration Application of Insane, INJECTION POWDER FOR SOLUTION , Subcutaneous

Dear Applicant -

Reference is made to the application for registration dated [date/month/year] : of the following product:

S.No	Product Name	Application Number
1	Insane, INJECTION POWDER FOR SOLUTION , Subcutaneous	NMFA/AR/2022/0002

This is to kindly inform you that evaluation of Insane, INJECTION POWDER FOR SOLUTION , Subcutaneous has been completed. In this regard, we are attaching herewith the queries for your reference and to respond not later than March 28th, 2022. Failure to respond by this date, the authority, at its discretion, will proceed to make a decision on the product for re-application of marketing authorization.

Best regards,

Iyassu Bahta  
Director, National Medicines and Food Administration  
Ministry of Health  
Asmara, Eritrea

## Queries to Applicant - for the Registration of **Insane, INJECTION POWDER FOR SOLUTION , Subcutaneous**

Upon evaluation of the dossier for the registration of **Insane, INJECTION POWDER FOR SOLUTION , Subcutaneous** , the following queries have been raised. Therefore, please address the following questions with the respect to the submitted product dossier.

### Module 1

<Section title> (<Page number>)

<insert your comments on the respective section of Module 1 here>

### Module 2

<Section title> (<Page number>)

<insert your comments on the respective section of Module 2 here>

### Module 3

<Section title> (<Page number>)

<insert your comments on the respective section of Module 3 here>

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