



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 [Month(text) date, year]. 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

<administrative information> (<Page number>)

<GMP certificate is not provided 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>

ቴሌ/ Tel. +291-1-125525
+291-1-125393

ፋክስ/ Fax +291-1-122899
ፋ.ሳ.ፖ. /P.O.Box 212



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