*CMDh/198/2010 Rev.4*

*February 2024*

**Decentralised Procedure**

**RMS Day 70 Preliminary Assessment Report**

**QUALITY**

**<Invented Name>**

**<(Active Substance)>**

**AB/H/{nnnn}/{nnn}/DC**

**Applicant:**

|  |  |
| --- | --- |
| **Reference Member State** |  |
| **Start of the procedure:** |  |
| **Date of this report:** |  |
| **Deadline for comments:** |  |

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List of Abbreviations

QUALITY CRITICAL ASSESSMENT

# REQUESTS FOR INSPECTION ACTION PRIOR TO AUTHORISATION

# INTRODUCTION

# DRUG SUBSTANCE

NOTES:

**-It should be mentioned whether a CEP or ASMF procedure or full information in the dossier of the Active Substance in the dossier is used.**

**In case the ASMF procedure is used it should be mentioned that the assessment of the Active Substance Master File (ASMF) is provided in a separate ASMF Assessment Report with a confidential annex on the Restricted Part.**

- Where there is more than one ASMF cited in the dossier, a separate report is provided for each ASMF

- Letters of Access in relation to specific drug products should be described for the product in question.

**- When a CEP or ASMF is used, only section III.4 Control of Drug Substance and III.5 Reference Standards or Materials relating to the product manufacturer need completing, unless the applicant has provided additional data e.g. 3.2.S.7 stability data to support a longer re-test period**

- The questions to the restricted part of the ASMF reports will not be sent to the Applicant but only to the relevant ASM/holder of the ASMF

- **Where ASMF or CEP is applicable, clarify the source (applicant or ASMF holder or CEP holder) and level of details to be drafted in the assessment report.**

**- The assessment of the drug substance in this AR should only address additional information provided by the applicant, which is not included in the ASMF. In case a full Module 3.2.S for the Active Substance is provided by the applicant, assessment of the active substance should be included in the day 70 PrAR.**

## General Information

## Manufacture (Letter of Access)

## Characterisation

## Control of Drug Substance

## Reference Standards or Materials

## Container Closure System

## Stability

# Drug Product

## Description and Composition of the Drug Product

## Pharmaceutical Development

## Manufacture

## Control of Excipients

## Control of Drug Product

## Reference Standards or Materials

## Container Closure System

## Stability

# APPENDICES

**A.1 Facilities and Equipment**

**A.2 Adventitious Agents Safety Evaluation**

**A.3 Novel Excipients**

# REGIONAL INFORMATION

**Process validation scheme for the drug product**

**Medical Device issues**

**TSE Issues**

# RMS’S COMMENTS ON THE SmPC, LABELS AND PACKAGE LEAFLET

# RMS’S OVERALL CONCLUSIONS ON QUALITY

***[New page]***

# LIST OF QUESTIONS AS PROPOSED BY THE RMS

**Major Objections**

**Drug Substance (related to additional data provided by applicant only)**

Note: In case the ASMF procedure is used the following should be stated in case major objections are being raised on the restricted part of the ASMF:

*“For major objections on the restricted part of the ASMF see separate AR on the ASMF”*

**Drug substance (applicant’s part as provided by ASMF holder)**

Note: Reference should be made to the separate AR on the ASMF as well

**Drug Product**

**Other concerns**

**Drug Substance (related to additional data provided by applicant only)**

Note: In case the ASMF procedure is used the following should be stated in case other concerns are being raised on the restricted part of the ASMF:

“*For other concerns on the restricted part of the ASMF see separate AR on the ASMF*”.

**Drug substance (applicant’s part as provided by ASMF holder)**

Note: Reference should be made to the separate AR on the ASMF as well

**Drug Product**