CONFIDENTIAL

NB: This Section should not be disclosed to the applicant

ANNEX 1- Restricted Part of the ASMF

Active Substance Master File (ASMF) Assessment Report

<(Active Substance)>

<ASM>

<EU/ASMF/<reference number>>

<Version Number applicant’s part dated>

<Version Number restricted part, dated>

|  |  |
| --- | --- |
| Centralised Procedure Number | EMEA/H/C/{nnnn}/{nnn}/{nnn}  |
| INN (or common name) of the active substance(s):  |  |
| ASM’s Internal API code (if applicable): |  |
| ASMF Holder (administration site):  | Name:Address: Contact person: Telephone:Telefax:E-Mail |
| ASM’s manufacturing facility(ies) name(s) and address(ses): | Manufacturer’s name:Address: Country: Telephone: Telefax: E-Mail:  |
| Date of ASMF Assessment Report[To be deleted as appropriate] | **<Initial Marketing application>**<Day 80 AR: ><Day 150 AR: ><Day 200 AR: >**<Type II Variation>**<Day 30 AR: ><Day 50 AR: >**<Type IB Variation>**<Day 20 AR: ><Day 40 AR: > |

**NOTES:**

**The structure of the report in this Annex should reflect the relevant parts of Module 3.2.S**

Table of contents

[Assessment Report and Questions on the Restricted Part of the ASMF 4](#_Toc486327420)

[S.1 General information 4](#_Toc486327421)

[S.2 Manufacture 4](#_Toc486327422)

[S.2.1 Manufacturer of drug substance (name, address and responsibility of each party, including contractors/intermediate(s) manufacturer(s) involved in the manufacturing chain) 4](#_Toc486327423)

[S.2.2 Description of the Manufacturing Process and Process Controls (detailed information) 4](#_Toc486327424)

[S.2.3 Control of Materials 4](#_Toc486327425)

[S.2.4 Control of Critical Steps and Intermediates 4](#_Toc486327426)

[S.2.5 Process Validation and/or Evaluation 4](#_Toc486327427)

[S.2.6 Manufacturing Process Development 4](#_Toc486327428)

[S.3 Characterisation 4](#_Toc486327429)

[S.3.2 Impurities 4](#_Toc486327430)

[S.4 Control of finished product 4](#_Toc486327431)

[S.4.5 Justification of Specification 4](#_Toc486327432)

[LIST OF QUESTIONS ON THE RESTRICTED PART OF THE ASMF AS PROPOSED BY THE Rapporteur(s) 5](#_Toc486327433)

[Assessment of Responses to the LIST OF QUESTIONS ON THE RESTRICTED PART OF THE ASMF 6](#_Toc486327434)

Assessment Report and Questions on the Restricted Part of the ASMF

**This Assessment Report solely concerns the ASMF**. It should however always be read in conjunction with the assessment report of the applicant’s part of the ASMF and the assessment report(s) of the Drug Product Application for the medicinal product for which it is associated with.

An ASMF in CTD-format has been provided by *{ASMF holder}* for the *{drug substance}:*

*Applicant’s Part version:*

*Restricted Part version:*

S.1 General information

S.2 Manufacture

S.2.1 Manufacturer of drug substance (name, address and responsibility of each party, including contractors/intermediate(s) manufacturer(s) involved in the manufacturing chain)

S.2.2 Description of the Manufacturing Process and Process Controls (detailed information)

S.2.3 Control of Materials

S.2.4 Control of Critical Steps and Intermediates

S.2.5 Process Validation and/or Evaluation

S.2.6 Manufacturing Process Development

S.3 Characterisation

S.3.2 Impurities

 If applicable according to NfG on ASMF

S.4 Control of finished product

S.4.5 Justification of Specification

If applicable according to NfG on ASMF

***OVERALL CONCLUSIONS ON THE Restricted PART OF THE ASMF***

## LIST OF QUESTIONS ON THE RESTRICTED PART OF THE ASMF AS PROPOSED BY THE Rapporteur(s)

Major Objections:

Other Concerns:

## Assessment of Responses to the LIST OF QUESTIONS ON THE RESTRICTED PART OF THE ASMF

Major Objections:

*Question*

*Summary of the Applicant’s Response*

*Assessment of the Applicant’s response*

*Overall Summary and Conclusion*

Other Concerns:

*Question*

*Summary of the Applicant’s Response*

*Assessment of the Applicant’s response*

*Overall Summary and Conclusion*

***OVERALL CONCLUSIONS ON THE Restricted PART OF THE ASMF***