ANNEX 1- Applicant’s 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  [delete for worksharing procedure for assessment of ASMF] | EMEA/H/C/{nnnn}/{nnn}/{nnn}  [delete for worksharing procedure for assessment of ASMF] |
| 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: > |

|  |  |
| --- | --- |
| Human use/Veterinary use or both |  |
| Maximum daily dose  (< 1 gram, < 10 grams, others specified)[[1]](#footnote-1) | e.g. < 1 gram, < 10 gram, others specified |
| Route(s) of administration. |  |
| Target/patient groups | Neonates/infants/children, adults |

**NOTES:**

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

**Where there is more than one ASMF cited in the dossier, a separate annex is needed for each ASMF**

**These annexes will not be sent to the MAH but only to the relevant ASM / holder of the ASMF**

**Letters of Access in relation to specific drug products are described in the Quality Assessment report for the product in question**

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Assessment Report and Questions on the Applicant’s 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 restricted 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 (name and address of the ASM)

S.2.2 Description of the Manufacturing Process and Process Controls (brief outline)

S.3 Characterisation

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OVERALL CONCLUSIONS ON THE Applicant’s PART OF THE ASMF

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

Major Objections:

Other Concerns:

## Assessment of Responses to the LIST OF QUESTIONS ON THE APPLICANTS 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 Applicant’s PART OF THE ASMF***

1. Reference source if other than the above Centralised application [↑](#footnote-ref-1)