[Choose appropriate title depending on evaluation stage]

Rapporteurs’ Day <106\*><150> Joint Assessment Report of the responses to the list of questions -Quality

Rapporteurs’ day <136\*><195> joint assessment report of the responses to the list of outstanding issues- Quality

\*in case of accelerated assessment

<Invented name>

<(Active substance)>

EMEA/H/C/<xxx>

For EU-M4all, procedure number is EMEA/H/W/xx

Applicant:

| <CHMP> <CAT> Rapporteur:  |  |
| --- | --- |
| <CHMP> <CAT> Co-rapporteur: |  |
| CHMP coordinator(s) *to be included only for CAT procedures* |  |
| EMA PL: |  |
| Start of the procedure: |  |
| Date of this report: |  |
| Deadline for comments: |  |

Note to the (Co)[Rapporteurs](https://www.ema.europa.eu/en/glossary/rapporteur%22%20%5Co%20%22One%20of%20the%20two%20members%20of%20a%20committee%20or%20working%20party%20who%20leads%20the%20evaluation%20of%20an%20application.%22%20%5Ct%20%22_blank): Assessment reports and comments should be circulated VIA EUDRALINK. Product Shared Mailbox: product.name-xxxx@ema.europa.eu and product initial MAA dedicated mailbox: MAAxxxx@ema.europa.eu (xxxx refers to the product number EMA/H/C/xxxx) should always be copied.

Declarations

This application includes an Active Substance Master File (ASMF):

[ ]  Yes

[ ]  No

[ ]  The assessor confirms that this assessment does **not** include non-public information, including commercially confidential information (eg. ASMF, information shared by other competent authorities or organisations, reference to on-going assessments or development plans etc), irrespective from which entity was received\*.

*\*If the entity from which non-public information originates has consented to its further disclosure, the box should be ticked and there* would *be no need to add details below.*

Whenever the above box is un-ticked please indicate section and page where confidential information is located here:

List of abbreviations

1. Assessment of the responses to the <CHMP> <CAT> List of <questions><outstanding issues>– Quality aspects

NOTES:

- 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. The ASMF assessment report prepared at Day 80 should be completed with the assessment of the responses to the <CHMP> <CAT> LoQ/LoOI

- Mention the EU ASMF reference number in this report.

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

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

- The assessment of the drug substance in this AR should only address additional information provided by the applicant, which is not included in the open part as provided by the ASMF holder. In case a full dossier for the Active Substance is provided by the applicant the full assessment of the active substance should be included in the day 180 AR.

* 1. Major objections
		1. 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”

 Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Drug Product

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* 1. Other concerns [related to additional data provided by applicant only]
		1. Drug substance

Note: When applicable: “For Other concerns on the restricted part of the ASMF see separate AR on the ASMF”

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Drug product

Question

Summary of the Applicant’s response

Assessment of the Applicant’s Response

Conclusion

1. Overall summary and conclusions on the Applicant’s Responses
	1. Unresolved Issues
2.
3. Annex 1 (as appropriate)

Active Substance Master File (ASMF) Assessment Report(s) – in separate document(s).