ASSESSMENT REPORT FOR MULTI-SOURCE (GENERIC) FINISHED PHARMACEUTICAL PRODUCTS (FPPS)

QUALITY PART OF DOSSIER

Date of assessment by rapporteur	
Date of plenary submission	
Rapporteur	
Application Reference Number(s) in rapporteur and other countries (where applicable)	
Date of submission to rapporteur	
Proprietary Product Name (if applicant)	
International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API), strength, pharmaceutical form.	
Conclusion of the assessment.	Additional data requested Recommended for registration
Name and complete address of the Applicant of the dossier	
Country A	
Country B	
Country C	
Country D	
Country E	
Name(s) and complete address(es) of the manufacturer (s) of the finished pharmaceutical product(s) [FPP(s)], including the final product release if different from the manufacturer.	
Name and address(es) of the manufacturer(s) of the API(s).	

LIST OF QUESTIONS (LOQ)

REQUESTS FOR FURTHER INFORMATION TO BE COMMUNICATED TO THE APPLICANT

These must reflect the outcome of the rapporteurs assessment and for the Consolidated Assessment Report (CAR) the list of questions (LOQ) from the plenary.

A. General remark, if applicable (e.g. structure, presentation etc. of the dossier)

B. Observations, information, questions

ACTIVE PHARMACEUTICAL INGREDIENT(S)
Observation, information, question 1)
Observation, information, question 2)
Observation, information, question 3)

FINISHED PHARMACEUTICAL PRODUCT
Observation, information, question 1)
Observation, information, question 2)
Observation, information, question 3)

Recommendations for inspection

Insert applicants submitted QOS below

Instructions for assessors.

The inserted copy of the QOS-PD from the applicant's dossier forms a major part of the rapporteurs report. The original text from the applicant is not modified but should be followed by the assessor's own critical assessment of these data, highlighting adherence to specific guidance documents.

The heading 'Assessor's Comments' should be introduced as a separator to avoid confusion

Assessors, where applicable, should seek advice or consult on cross cutting issues (Quality vs Safety/Efficacy) and include summary of such consultation in the assessment report.

For each item assessed the rapporteur should as much as possible state the number of the corresponding page of the dossier where this item can be found. This is to facilitate the 2nd review should they wish to consult the dossier.

Discuss/interprete results giving the grounds for the benefit-risk assessment, recommendations and questions posed to the applicant. Comments made to the applicant should be written in unambiguous language and as much as possible should include references to applicable guidelines or standards. When possible, comments may also include suggestions or recommendations on how to address the observed deficiency.

In the assessment report (with applicant's text in BLACK) all comments by the Rapporteur must be written in RED. The comments from the Plenary should be written in BLUE. The **"Requests for further information"** should be written in full by the Rapporteur and highlighted in YELLOW. NO OTHER COLOURS MUST BE USED.

Current applicable commitments

State here any proposed and accepted commitments from the applicant/manufacturer e.g. stability, process validation etc.

Latest reviewed API and FPP specifications

Insert Copy of API specification

Insert Copy FPP release specification

Insert Copy of FPP Shelf life specification