Part 5 **Evaluation Form 5 -**

for use in checking that the *Tier I* quality checks for individual tests and studies are of acceptable quality [1]

Active Substance
Applicant:
Date:

Test or Study Point	Description of the requirement	Provided Y/N[#]
1.1	The Annex IIP or Annex IIIP point addressed	__
1.2	A descriptive title of the type of test or study	__
2	Reference point (location) of the report in the dossier (*e.g.* volume, section and Annex point)	__
3.1	The names of the authors	__
3.2	The title of the report	__
3.3	The owner of the test or study report	__
3.4	An indication as to whether it is a published or unpublished report	__
3.5	The report number	__
3.6	The date of the report	__
4.1	The name and address of the testing facility	__
4.2	The laboratory report/project number	__
5.1	The dates of commencement and completion of experimental work	__
5.2	A statement of the objectives of the test or study	__
6.1	The identity of the test substance or material (ISO common name, batch number and degree of purity)	__
6.2	An explicit reference to the relevant specification of composition of the test substance or material	__
6.3	Where available, data relevant to the storage stability of the test substance or material	__

[#] Y = yes; N = no

[1] Relevant for tests and studies for which the test methods used were not those currently specified (*e.g.* certain older studies)

Active Substance: **Applicant:** **Date:**

Test or Study Title: **Annex Point:**

Test or Study Point	Description of the requirement	Provided Y/N
6.4	Where relevant and available, data as to the stability of the test substance or material in the dosing vehicle	__
6.5	Where relevant and available, data as to the homogeneity of the test substance or material in the dosing or testing vehicle	__
6.6	Where data relating to the stability or homogeneity of the test substance is not available (*e.g.* certain older studies), a justification of the scientific validity of the study	__
6.7	Where relevant, information as to the physical form of the test substance or material	__
6.8	Full details of the composition of any dosing vehicles or solvents used	__
7.1	The identity of the test method used	__
7.2	Where not a method specified in Annex II, or Annex III, a reasoned justification for the choice of method used in terms of its scientific validity and comparability with the method specified in Annex II or Annex III	__
7.3	On request, a copy of the method - full details of methods used which are unlikely to be accessible to competent authority of the Member State to which the dossier is submitted, should be attached to the study or test report	__
7.4	Where test guidelines provide choice as to the method to be used, a reasoned justification for the choice made	__
7.5	Where deviations from the test guidelines specified, or from other methods used, are employed, a description of and reasoned justification for the deviations	__
8.1	Where relevant, an indication as to whether, or not, the test or study has been conducted by a laboratory certified as to its competence to conduct the test or study in compliance with the principles of GLP	__
8.2	Where relevant, the certifying authority	__
8.3	Where applicable, an indication as to whether, or not, the principles of GLP have been complied with	__
8.4	Where relevant, a justification for non compliance with the principles of GLP	__
9.1	Where relevant, a clear statement that the requirements of points 2.2 and 2.3 of the introduction to Annex III have been complied with - Good Experimental Practice (GEP)	__

Active Substance: **Applicant:** **Date:**

Test or Study Title: **Annex Point:**

Test or Study Point	Description of the requirement	Provided Y/N
9.2	Where the requirements of points 2.2 and 2.3 of the introduction to Annex III apply, whether conducted by an official or an officially recognized testing facility or organization	__
9.3	Where relevant, a justification for non compliance with the requirements of points 2.2 and 2.3 of the introduction to Annex III	__
10	A description of the test system	__
11	The identity of any statistical and other techniques applied to the data to aid interpretation, together with adequate documentation thereof and a justification for the use of the technique selected where non standard techniques are used	__
12.1	Where reference to published papers is made in *Tier I* checks as to the quality of individual test and study reports, the bibliographic references concerned	__
12.2	On request, copies of the papers concerned	__
13	Where reference to unpublished data is made in *Tier I* checks as to the quality of individual test and study reports (*e.g.* historical control data on strains of test animals) a summary of such data	__

Assessment of the Acceptability of the Quality of the Report

Report of acceptable quality Yes No

Comments:

Signature: