

**Biowaiver Assessment Report for**

**Emulsions for Intravenous Injection**

**Bioequivalence Working Group for Generics**

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**Disclaimer**

This document reflects the views of subject matter experts participating in the IPRP Bioequivalence Working Group for Generics (BEWGG) and should not be construed to represent the official view of any given regulatory authority participating in the IPRP.

**Biowaiver Assessment Report for**

**Emulsions for Intravenous Injection**

**<Proposed proprietary name>**

**<API> <Product strength(s)> <Product dosage form>**

**<Application/Dossier reference number>**

**Applicant:** **<Name of the Applicant>**

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# GLOSSARY / ABBREVIATIONS

**API, Drug** Active pharmaceutical ingredient / Drug substance

**BE** Bioequivalence

**Drug product** Pharmaceutical product / Medicinal product / Medicine/ Final product

# SUMMARY: REQUIREMENTS and OUTCOMES

|  |  |
| --- | --- |
| **Requirements** | **Outcome** |
| **Dosage form** | Emulsion for injection |
| **Route of Administration** | Intravenous |
| **Qualitative composition of the excipients compared to the Comparator Product** | Sufficiently similar / Unacceptable differences |
| **Quantitative composition of the excipients compared to the Comparator Product** | Sufficiently similar / Unacceptable differences |
| **Physicochemical properties** | Sufficiently similar / Unacceptable differences |
| **Conclusion** | Approvable / Non-approvable |

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| *Note:*  *The waiver requirements described here relate to products that are administered as emulsion formulations that are not intended to control release or disposition and the method and rate of administration is the same as that of the comparator product* |

# ASSESSMENT OF THE BIOWAIVER

## Application objective

Clearly state the regulatory/scientific basis for the biowaiver request for the proposed product.

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| ***Assessor’s comments:*** *<Please comment here>* |

## Comparator product

State the relevant details of the comparator product for the application, e.g. product name, dosage form, strengths, marketing authorisation holder.

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| ***Assessor’s comments:*** *<Please comment here>* |

## Nature of the dosage form

Clearly state the nature of the proposed dosage form and if it is the same dosage form as the Comparator Product. If not, please justify.

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| ***Assessor’s comments:*** *<Please comment here>* |

## Qualitative and quantitative composition (Proposed Product vs Comparator Product)

A listing of the excipients in the proposed product and comparator product and their quantities should be provided. If there are differences in excipients (e.g. hydration form, polymorphism, viscosity grade), these should be clearly listed.

The following table can be replicated for each product strength, if needed.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Component** | **Function** | **Proposed Product**  **Composition (unit)** | **Comparator Product**  **Composition (unit)** | **% difference**  **(test/comparator)** | **Maximum amount per dose or MDD\*** | **IID limit\*** |
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\*if there are qualitative/quantitative differences in any component; MDD: Maximum daily dose; IID: Inactive Ingredient Database

☐ Yes ☐ No The qualitative composition of the proposed product and the comparator product is the same.

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| ***Assessor’s comment:*** *<If No, please describe and explain if such differences are acceptable or not>* |

☐ Yes ☐ No The quantitative composition of the proposed product and the comparator product is the same.

Ideally, the quantitative composition should be quantitatively the same between the proposed product and the comparator product. Any quantitative differences may need to be further explained.

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| ***Assessor’s comment:*** *<If No, please describe and explain if such differences are acceptable.>* |

## Physicochemical properties (Proposed Product vs Comparator Product)

Physicochemical comparability should be discussed in each respective section below.

Details on the expected data should be provided, e.g. batch numbers, number of batches/samples, any statistical analysis results (such as mean, %CV, population BE analysis on globule size distribution).

Add further parameters as required. Not all parameters may be required in certain markets.

1. **pH**

XX

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| --- | --- | --- | --- |
| **Product** | **Observed result** | **Mean (%CV)** | **Mean Ratio (Tolerance)** |
| Comparator | Experiment 1  Experiment 2  Experiment 3 |  |  |
| Test | Experiment 1  Experiment 2  Experiment 3 |  |

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| ***Assessor’s comments:*** *<Please comment here>* |

1. **Osmolarity**

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*The table in A. pH can be replicated in this and the following sections as needed.*

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| ***Assessor’s comments:*** *<Please comment here>* |

1. **Viscosity/rheological properties (viscosity profile as a function of applied shear)**

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| ***Assessor’s comments:*** *<Please comment here>* |

1. **Droplet size distribution in dispersed lipid phase**

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| ***Assessor’s comments:*** *<Please comment here>* |

1. **Specific gravity**

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| ***Assessor’s comments:*** *<Please comment here>* |

1. **Surface Properties (zeta potential of the formulation and at physiological pH)**

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| ***Assessor’s comments:*** *<Please comment here>* |

1. **Distribution of the drug in the aqueous and oil phase of the formulation**

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| ***Assessor’s comments:*** *<Please comment here>* |

1. **Other physicochemical properties (e.g. free acid concentration for propofol and clevidipine)**

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| ***Assessor’s comments:*** *<Please comment here>* |

* 1. **In vitro drug release tests (Proposed Product vs Comparator Product)**

The methodology used for *in vitro* drug release testing should be described in sufficient detail.

Details on the expected data should be provided, e.g. parameters, number of batches/samples, any statistical analysis results (such as mean, %CV), f2 or other suitable method for release data comparison.

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| ***Assessor’s comments:*** *<Please comment here>* |

# LIST OF OUTSTANDING ISSUES / DEFICIENCIES / PROPOSED QUESTIONS

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| ***Assessor’s comments:*** |

# CONCLUSIONS AND RECOMMENDATIONS

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