

**Biowaiver Assessment Report for**

**Solutions for Intramuscular and/or Subcutaneous Injection**

**Bioequivalence Working Group for Generics**

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| Version | Description of Change | Author | Effective Date |
| v 1 | Original publication | BEWGG | 7 Nov 2024 |
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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**

**Solutions for Intramuscular and/or Subcutaneous 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

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

# SUMMARY: REQUIREMENTS and OUTCOMES

|  |  |
| --- | --- |
| **Requirements** | **Outcome** |
| **Dosage form** | e.g., Aqueous injection solution, Oily injection solution |
| **Routes of Administration** | Intramuscular/Subcutaneous |
| **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 also apply to powders for subcutaneous or intramuscular injection solutions that are administered as solutions after reconstitution.* |

# 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>* |

## Posology and administration

Comment on whether the proposed product and comparator product have the same volume and site of administration, as changes may result in clinical differences (safety).

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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.

Ideally, the excipient composition should be qualitatively the same between the proposed product and the comparator product. In general, excipients affecting viscosity, surfactants and complexing agents should not be changed.

If there are qualitative differences in the compositions, any potential impact on bioavailability should be further explained. Some qualitative differences, e.g. buffer agents, antioxidants and preservatives may be acceptable if scientifically justified. For oily injection solutions, the same oily vehicle is expected.

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| ***Assessor’s comment:*** *<describe and explain if differences are acceptable>* |

☐ 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, but quantitative similarity may be accepted. The levels of excipients may have special considerations in vulnerable patient populations, e.g. benzyl alcohol and propylene glycol should not be greater in injections that can be used in neonates and infants.

If there are quantitative differences in the compositions, any potential impact on pharmacokinetics/bioavailability should be further explained.

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| ***Assessor’s comment:*** *<describe and explain if 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).

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

1. **pH**

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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. **Osmolality**

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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**

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

1. **Buffer capacity**

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

1. **Other physicochemical properties**

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

# LIST OF OUTSTANDING ISSUES / DEFICIENCIES / PROPOSED QUESTIONS

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# CONCLUSIONS AND RECOMMENDATIONS

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