

**Biowaiver Assessment Report for**

**Soft Gelatin Capsules**

**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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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**

**Soft Gelatin Capsules (Liquid Contents)**

**<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

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| --- | --- |
| **Requirements** | **Outcome** |
| **Dosage form** | Soft gelatin capsule (liquid contents) |
| **Routes of Administration** | Oral |
| **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 |

# ASSESSMENT OF THE BIOWAIVER

## Application objective

Clearly state the regulatory/scientific basis for the biowaiver request for the proposed product. A biowaiver may be considered if the drug substance is in solution inside the capsule and the gelatin coating is fast-dissolving.

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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 state 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.

In general, the excipient composition of the fill liquid should be qualitatively the same between the proposed product and the comparator product.

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

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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.

In general, the quantitative composition of the fill liquid should be quantitatively the same or quantitatively similar between the proposed product and the comparator product.

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 of capsule contents**

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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. **Viscosity of capsule contents**

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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>* |

## 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. number of batches/samples, any statistical analysis results (such as mean, %CV), f2 or other suitable method for release data comparison.

1. **In vitro disintegration / dissolution profiles at pH 1.2 to 6.8**

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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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