Zinc Products: Biowaiver Application

General Instructions:

Please review all the instructions thoroughly and carefully prior to completing the application form. Ensure that all sections of the form are completed in their entirety.

Provide as much detailed, accurate and final information as possible. Note that the greyed areas are NOT to be filled in by the applicant but are for WHO use ONLY!

Please state the exact location (Annex number) of appended documents in the relevant sections of the application form.

Before submitting the completed Biowaiver Application Form, kindly check that you have provided all requested information and enclosed all requested documents.

Should you have any questions regarding this Form, please contact WHO Prequalification of Medicines Programme via e-mail at [prequalassessment@who.int](mailto:prequalassessment@who.int).

A properly completed and signed original copy of the application form with all its annexes (including a copy on CD-ROM) must be submitted to the Prequalification Programme together with the bioequivalence part of the dossier. Please provide the document as an MS Word file. As always, the dossier with the application (plus annexes) should be sent to the sent to the address provided on the programme’s website.

Administrative data

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| --- |
| 1. INN of active ingredient(s)   *< Please enter information here >* |
| 1. Dosage form and strength   *< Please enter information here >* |
| 1. Product WHO Reference number (if product dossier has been accepted for PQ assessment)   *< Please enter information here >* |

|  |
| --- |
| 1. Name of applicant and official address   *< Please enter information here >* |

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| 1. Name of manufacturer of finished product and official address   *< Please enter information here >* |

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| 1. Name and address of the Contract Research Organization(s) where the any supporting studies were conducted.   *< Please enter information here >* |

I, the undersigned, certify, that the information provided in this application and the attached documents is correct and true

Signed on behalf of <company>

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Name and title)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Date)

BIOWAIVER APPLICATION FORM

# Test product

## Tabulation of the composition of the formulation proposed for marketing and those used for solubility study

* Please state the location of the master formulae in the quality part of the submission.
* Tabulate the composition of each product strength using the table below.
* For solid oral dosage forms the table should contain only the ingredients in tablet core.

**Please note:** If the formulation proposed for marketing and those used for solubility studies are not identical, copies of this table should be filled in for each formulation with clear identification in which study the respective formulation was used.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Composition of the batches used for dissolution studies | | | | |
| Batch number |  | | | |
| Batch size (number of unit doses) |  | | | |
| Date of manufacture |  | | | |
| Comments, if any | | | | |
| Comparison of unit dose compositions and of clinical FPP batches  (duplicate this table for each strength, if compositions are different) | | | | |
| Ingredients (Quality standard) | Unit dose (mg) | Unit dose (%) | Biobatch (kg) | Biobatch (%) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Equivalence of the compositions or justified differences |  | | | |

## Potency (measured content) of test product as a percentage of label claim as per validated assay method

This information should be cross-referenced to the location of the Certificate of Analysis (CoA) in this biowaiver submission.

*<< Please enter information here >>*

## Excipients

**Identify any excipients present in the proposed product that may impact in vivo absorption of zinc. All sweeteners present in the formulation should be identified and evidence that they will not negatively affect the absorption of zinc from the formulation should be provided.**

Empirical data or literature-based information establishing the positive, negative, or negligible impact of the excipients on zinc should be included, and a full discussion of the impact should be presented.

*<< Please enter information here >>*

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| Comments from review of Section 1 – WHO use only |
|  |

# Solubility Testing

* A detailed summary of the solubility studies conducted and the results obtained should be included below. Complete information, data, results, and conclusions for the solubility testing should be provided in the Quality portion of the dossier. The solubility study will be reviewed during the assessment of the Quality part of the dossier.

*<< Please enter information here >>*

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| Comments from review of Section 2 – WHO use only |
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| CONCLUSIONS AND RECOMMENDATIONS – WHO use only |
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