Zinc Product:

Acceptability Study Summary Form

**General Instructions:**

Please review all the instructions thoroughly and carefully prior to completing the application form. Ensure that all sections 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 Zinc Products: Acceptability Study Summary 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.

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 Team: medicines (PQTm) together with the bioequivalence part of the dossier. Please provide the document as an MS Word file. The dossier with the application (plus annexes) should be sent to the sent to the address indicated in the Procedures & Fees section of the PQTm website.

**Administrative Data**

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| --- |
| **1. International nonproprietary name (INN) of active ingredient(s)**  *< Please enter information here >* |
| **2. Dosage form and strength**  *< Please enter information here >* |
| **3. Product WHO reference number** *(if product dossier has been accepted for PQ assessment)*  *< Please enter information here >* | |
| **4. Name of applicant and official address**  *< Please enter information here >* | |
| **5. Name of manufacturer of finished product and official address**  *< Please enter information here >* | |
| **6. Name and address of the contract research organization(s) where the any supporting studies were conducted**  *< Please enter information here >* | |
| **7. Name and address of the contract research organization(s) responsible for the conduct of the acceptability study**  *< 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>***

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

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

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| **Acceptability Study Summary**   |  | | --- | | **A.1 Summary of the acceptability study information**  The summary provided below should include details concerning the study design, implementation, data analysis, results, and conclusions. | | **A1.1.1 Provide the study title and study identification number**  *< Please enter information here >* | | **A1.1.2 Please state the location of:**   * the acceptability study protocol in this application * the acceptability study report in this application   *< Please enter information here >* | | | **A.1.3 Summarize the study design, the subject population, and the logistics of study conduct including facilities employed, study dates, and locations**  *< Please enter information here >* | | | **A.1.4 Summarize the study results and data analysis conducted**  *< Please enter information here >* | | | **A.1.5 Summarize the conclusions of the acceptability study**  *< Please enter information here >* | | | **A.2 Comments from review of PART A – WHO use only** | | |  | | | **B. CONCLUSIONS AND RECOMMENDATIONS – WHO use only** | | |  | | |