Applicants Address

Generic name of product, strength and dosage form:
Proposed Trade name:

(Insert name of applicant) hereby submits our application for registration of *(insert Generic name, strength and dosage form of product)* to be considered under the ZaZiBoNa collaborative registration procedure in response to the *(insert number of applicable EoI e.g. 1st)* Expression of Interest to register medicinal products via the ZaZiBoNa collaborative process.

We hereby confirm that we are interested in the Authority managing the application in line with principles of ZaZiBoNa.

We also confirm our to consent to sharing of the product related information among all Zazibona authorities during the registration process and post-registration.

We also confirm that the same application is being submitted concurrently to the following countries

1.
2.
3.

I, the undersigned, hereby declare that all the information contained herein and in the appendices is true, complete and correct.

Full Name and Title of applicant representative

Title or Responsibility

Signature of applicant representative

Date

Submission Checklist

(To be completed for each application and strength and to accompany the cover letter)

We hereby confirm that the following key information is included with this submission

	Information submitted *(please comment below, if requirements not fully met)*	***YES***	***NO***
This product and strength is included in the current ZaZiBoNa expression of interest			
Comment			
A valid Manufacturing Licence and/or valid GMP certificate for the FPP is/are included.			
Comment			
Valid marketing authorization data is included			
Comment			
Prequalified-API or CEP is used to present API data, and respective CPQ, Letters of Access or EDQM CEP are provided			
Comment			
If case API data is submitted in full for an API site a declaration has been provided from the API manufacturer that: a) They have provided to the FPP manufacturer all confidential and non-confidential information regarding the preparation, control and stability of the API as per ICH module 3.S.2; b) They will inform the FPP manufacturer of any changes to the preparation, control and stability of the API.			
Comment:			
The QOS-PD and QIS are provided as Word documents.			
Comment			
In case bioequivalence study is required (no biowaiver application), the BTIF is provided as a Word document.			
Comment			
In case biowaiver application is requested, the BW-BCS or BW-BCW Additional Strength form is provided as a Word document.			
Comment			
At the time of submission, is the stability data available for at least 6 months at the accelerated condition and 12 months at the long-term condition and for at least 2 pilot scale batches.			
Comment			
Data is presented on validation of FPP manufacturing process			
Comment			
Copies of executed biobatch and proposed blank master production record(s) for commercial production batch(es) are included in the CTD Dossier.			
Comment			
Data on validation or (where applicable verification) of analytical procedures for the API and FPP are included in the CTD dossier.			
Comment			