(Made under the Regulation 4 (1))

Application Number	TMDA use only
Date of submission of the dossier	TMDA use only

1.0	**ADMINISTRATIVE AND PRODUCT INFORMATION**
1.1	Type of the medicinal product application New Renewal* * If variation has been made, information supporting the changes should be submitted (See TMDA variation guidelines for registered medicinal products)
1.2	Botanical name of the plant from which herbal substance is obtained
1.3	Active herbal Substance and solvent used for extraction e.g cinchona root bark 80% aqueous ethanol
1.4	Strength of Active Herbal Substance per unit dosage form
1.5	Name and address (physical and postal) of Applicant
(Company) Name: Address: Country: Telephone: Telefax: E-mail:	
1.6	Name and address (physical and postal) of Applicant
(Company) Name: Physical Address: Postal address Region Country: Telephone: Telefax: E-mail:	
1.7	Dosage form and route of administration
1.7.1	Dosage form:
1.7.2	Route(s) of administration
1.8	Packing/pack size:
1.9	Visual description (Add as many rows as necessary)

1.10	Proposed shelf life (in months):
1.10.1	Proposed shelf life (after reconstitution or dilution):
1.10.2	Proposed shelf life (after first opening container):
1.10.3	Proposed storage conditions:
1.10.4	Proposed storage conditions after first opening:
1.11	Other sister medicinal products registered or applied for registration
1.11.1	Do you hold Marketing Authorization(s) of other medicinal product(s) containing the same herbal substance(s) in the TMDA? If yes state; ▪ Product name(s), strength(s), pharmaceutical dosage form(s): ▪ Partner States where product is authorized: ▪ Marketing authorization number(s): Indication(s):
1.11.2	Have you applied for marketing authorization medicinal product(s) containing the same active substance(s) in the TMDA? If yes state; ▪ Product name(s), strength(s), pharmaceutical dosage form(s): Indication(s):
1.12	Pharmacotherapeutic group and ATC Code
1.12.1	Pharmacotherapeutic group:
1.12.3	If no ATC code has been assigned, please indicate if an application for ATC code has been made:
1.13	Distribution category: Controlled Drug ☐ POM ☐ Pharmacy Only ☐ OTC ☐ General sale ☐ (Applicants are invited to indicate which categories they are requesting, however, the NMRAs reserve the right to change and/or apply only those categories provided for in their national legislation)
1.14	Country of origin:
1.12	Pharmacotherapeutic group and ATC Code
1.12.1	Pharmacotherapeutic group:
1.12.3	If no ATC code has been assigned, please indicate if an application for ATC code has been made:
1.13	Distribution category: Controlled Drug ☐ POM ☐ Pharmacy Only ☐ OTC ☐ General sale ☐ (Applicants are invited to indicate which categories they are requesting, however, the NMRAs reserve the right to change and/or apply only those categories provided for in their national legislation)
1.14	Country of origin:
1.15	Product Marketing Authorization in the country of origin (Attach Certificate of Pharmaceutical Product or free sale certificate from National Medicines Regulatory Authority). If not registered, state reasons

☐ Date of authorization (dd-mm-yyyy): Proprietary name: Authorization number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorization) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: Date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

1.16	Name(s) and complete physical address(es) of the manufacturer(s)
1.16.1	**Name(s) and physical address (es) of the manufacturing site of the finished herbal product (FPP), including the final product release if different from the manufacturer. Alternative sites should be also declared here.** state the role of each site (Add as many rows as necessary)

Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.16.2	**Name(s) and physical address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s) (API)** (Add as many rows as necessary) All manufacturing sites involved in the manufacturing process of the herbal substance should be listed.
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.17	Name and address (physical and postal) of the local

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

1.18	State the reference/monograph standard such as WHO monograph of selected medicinal plants, British Pharmacopeia, United States Pharmacopeia, Ph. Eur, Japanese Pharmacopeia, In-house monograph e.t.c. used for herbal substance
1.19	Qualitative and Quantitative composition of the active substance(s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. 1 capsule).

Name of active ingredient(s)*	Quantity / dosage unit	Unit of measure	Reference/ monograph
1.			
2.			
3.			
4.			
e.t.c			
Name Excipient(s)			
1.			
2.			
3.			
4.			
e.t.c			

1.20	Name and address (physical and postal) of the Contract Research Organisation (s) where the clinical studies of the product were conducted.

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

2.0 DECLARATION BY AN APPLICANT

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.

I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the TMDA.

I further agree that I am obliged to follow the requirements of the TMDA Legislations and Regulations which are applicable to medicinal products.

I also consent to the processing of information provided by the TMDA.

It is hereby confirmed that fees will be paid/have been paid according to the TMDA Fees and Charges Regulations*

Name: ……..…….
Position in the company:……
Signature: ……..……
Date:……..
Official stamp:……..

* Note: If fees have been paid, attach proof of payment