APPLICATION FOR REGISTRATION OF MEDICINAL PRODUCT

(Made under Regulation 5(1) (b) and 16(1))

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

ADMINISTRATIVE INFORMATION

PARTICULARS OF THE PRODUCT

1.0	Product category: Human medicine: Veterinary medicine:
1.1	Type of the medicinal product application New: Renewal* : Indicate registration number: ** If variation has been made, information supporting the changes should be submitted. See TMDA variation guidelines for registered medicinal products.*
1.2	Proprietary Name:
1.3	International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API):
1.4	Strength of Active Pharmaceutical Ingredient (API) per unit dosage form:
1.5	Name and address (physical and postal) of Applicant:

(Company) Name:

Address:
Country:
Telephone:
Telefax:
E-Mail:

1.6	Pharmaceutical Dosage form* and route of administration* * List of standard terms for dosage forms and routes of administration is available in the TMDA guidelines on submission of documentation for registration of human medicinal products.
1.6.1	Dosage form:
1.6.2	Route(s) of administration (use current list of standard terms)
1.7	Packing/pack size:
1.8	Visual description *(Add as many rows as necessary)*
1.9	Proposed shelf life (in months):
1.9.1	Proposed shelf life (after reconstitution or dilution):
1.9.2	Proposed shelf life (after first opening container):
1.9.3	Proposed storage conditions:
1.9.4	Proposed storage conditions after first opening:
1.10	Other sister medicinal products registered or applied for registration
1.10.1	Do you hold Marketing Authorization (s) of other medicinal product (s) containing the same active substance (s) in the TMDA? If yes state; _ Product name (s), strength (s), pharmaceutical form (s): _ Partner States where product is authorised: _ Marketing authorisation number(s): _ Indication(s):
1.10.2	Have you applied for Marketing Authorization of medicinal product (s) containing the same active substance (s) in TMDA? _ Product name (s), strength (s), pharmaceutical form (s): _ Indication(s):
1.11	Pharmacotherapeutic group and ATC Code:
1.11.1	Pharmacotherapeutic group:

1.11.2	ATC Code: (*Please use current ATC code)*
1.11.3	If no ATC code has been assigned, please indicate if an application for ATC code has been made:
1.12	Distribution category: Controlled Drug POM Pharmacy Only OTC General sale *(Applicants are invited to indicate which categories they are requesting, however TMDA reserves the right to change and/or apply only those categories provided for in their national legislation)*
1.13	Country of origin:
1.14	Product Marketing Authorisation in the country of origin (Attach Certificate of Pharmaceutical Product from National Medicines Regulatory Authority). If not registered, state reasons:

☐ Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) 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:

1.15	List ICH countries and Observers where the product is approved (attach evidence):
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 pharmaceutical product (FPP), including the final product release if different from the manufacturer. Alternative sites should be also declared here: *All manufacturing sites involved in the manufacturing process of each step of the finished product, stating the role of each including quality control / in-process*

	testing sites should be listed. (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 each source of active substance, including quality control / in-process testing sites should be listed.*
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.17	Name and address (physical and postal) of the Local Technical Representative (LTR)
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.18	Name and address (physical and postal) of the person or company responsible for pharmacovigilance:

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

1.19	State the reference/monograph standard such as British Pharmacopeia, United States Pharmacopeia (USP), European Pharmacopeia (Ph.Eur), Japanese Pharmacopeia (JP), International Pharmacopeia (Ph.Int), In-house monograph e.t.c. used for Finished Medicinal Product:
1.20	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 standard
1.			
2.			
3.			
e.t.c			
Name Excipient(s)			
1.			
2.			
3			
e.t.c			

*Note: * Only one name for each substance should be given in the following order of priority: INN**, Pharmacopoeia, common name, scientific name*
*** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.*
Details of averages should not be included in the formulation columns but should be stated below:
- Active substance(s):
- Excipient(s):

1.21	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the product were conducted. *(If applicable):*

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

DECLARATION BY THE 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 TMDA.
I further agree that I am obliged to follow the requirements of the Legislations and Regulations which are applicable to medicinal products. I also consent to the processing of information provided by TMDA.

It is hereby confirmed that fees have been paid according to the Fees and Charges Regulations.

Name:
_____
Position in the company: _____
Signature:
_____
Date:
_____
Official stamp: _____

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