Application Number	
Date of submission of the dossier	
Number of files	
Name of First Assessor	
Name of Second Assessor	
Date of first Assessment	
Date of second Assessment	
Outcome of the assessment	

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐ Medicated Soap ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant and Local Technical Representative
1.5.1	Name and address (physical and postal) of Applicant
	(Company) Name: Address: Country: Telephone: Telefax: E-Mail:
1.5.2	Name and address (physical and postal) of Local Technical Representative
	(Company) Name: Address: Country: Telephone: Telefax: E-Mail:
1.6.	Form of the product: ☐Solution ☐Suspension ☐Gel ☐Aerosol ☐Emulsion ☐Gaseous ☐Powder ☐Bar ☐Tablet ☐ Cream ☐Others – specify....
1.6.1	Intended use:
1.7	Packing/pack size:
1.8	Visual description
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 products registered or applied for registration
1.10.1	Do you hold Marketing Authorization (s) of other product (s) containing the same active substance (s) in the TMDA? Yes/No If yes state; Product name (s), strength (s), pharmaceutical form (s): Indication(s):
1.10.2	Have you applied for Marketing Authorization medicinal product (s) containing the same active substance (s) in the TMDA? Yes/No If yes state; Product name (s), strength (s), pharmaceutical form (s): Indication(s):
1.11	Distribution category: Pharmacy Only ☐ General sale ☐ Others☐
1.12	Country of manufacture:
1.13	Product Marketing Authorisation in the country of manufacture. If not registered/licensed state reasons

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Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent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

1.14	Name(s) and complete physical address(es) of the manufacturer(s)
1.14.1	Name(s) and physical address (es) of the manufacturing site of the finished product.

Company name:
Physical address:
Postal address:
Country:
Telephone:
Telefax:
E-Mail:

1.14.2	Name(s) and physical address(es) of the manufacturer(s) of the active substance(s)

Company name:
Physical address:

Postal address: Country: Telephone: Telefax: E-Mail:	
1.15	Qualitative and Quantitative composition (active substance (s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. ml or g).

Name of active substance(s)*	Reference/monograph standard	Quantity /unit (ml, g)	Quantity per batch	Reasons of inclusion
1.				
2.				
3.				
e.t.c				
Name Excipient(s)				
1.				
2.				
3				
e.t.c				

2.0 LABELLING

3.0 SUMMARIES

Provide condensed summaries of the key quality, efficacy and safety information from the product dossier. The summaries should include sufficient information from each section of the product dossier to provide an overview of the information submitted in the product dossier. The summaries should also emphasize critical key parameters of the product and provide discussion of key issues that integrates information from sections in the product dossier.

Chemistry, Manufacturing and Controls

	Chemistry
	Manufacturing process

	Quality control
	Specifications and analytical methods
	Stability studies
Efficacy and Safety	
	Efficacy
	Safety
Data to support specific claims (for antiseptics)	
	Products used in professional food premises
	Log reduction claims
	Persistence claims
	Time kill claims
	Sterility

4.0 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 also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to TMDA.
It is hereby confirmed that fees will be paid/have been paid according to the TMDA fees and regulation
Name: ……..…….
Position in the company:……
Signature: ……..……
Date:……..
Official stamp:……..

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

Issues to be communicated to the applicant