NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

SCREENING TEMPLATE FOR NEW APPLICATIONS FOR REGISTRATION

The Screening Template is to be used on receipt of an application for registration of a medicinal product for human or veterinary use submitted to the ***Namibia Medicines Regulatory Council***.

A separate application for each strength and pharmaceutical form is required.

A ADMINISTRATIVE

Product and dossier information (C = Critical)			
1	Applicant	**C**	<name and address plus email address>
2	Product reference number		<Screening number>
3	Product name	**C**	<Proprietary name, Active ingredient, strength; pharmaceutical form>
4	Date of letter of application*		
5	Date of receipt		<date submitted>
6	Screening fee included (proof of payment)	**C**	Y ☐ N ☐
7	Is the dossier correctly bound? (No lever arch files, no ring binders, 4 cm thick but not over-full for the binder	**C**	Y ☐ N ☐

Product and dossier information (C = Critical)				
	used)*			
8	Has the applicant submitted the dossier in CTD format in hard copy (Module 1) and electronic i.e. CD or DVD (All Modules)?	**C**	Y ☐	N ☐
9	Have dividers been included in the paper submission?	**C**	Y ☐	N ☐
10	Are at least 3 samples in the smallest pack included?	**C**	Y ☐	N ☐
11	Is the application form signed by the authorized pharmacist, and dated?	**C**	Y ☐	N ☐

* Paper submissions

B TECHNICAL VERIFICATION – PHARMACEUTICAL QUALITY

Critical Pharmaceutical Quality Information		Yes (Y)	No (N)
1	**Active pharmaceutical ingredient (API):**		
1a	Has the applicant provided the APIMF/WHO API or CEP with letters of access?		
1b	Is the stability data submitted for accelerated and long term conditions for all declared API(s) sources?		
1c	Has the applicant submitted Namibian QOS-PD in word format in the electronic submission?		
2	**Finished Pharmaceutical Product (FPP):**		
2a	Is Module 3.2.P for each manufacturer of FPP included?		
2b	Is the stability data submitted for accelerated and long term conditions (In case of line extensions, stability data for all strengths should be submitted)[α]		

[α] Long term stability study for FPP should be done in accordance with climatic Zone IV conditions.

C TECHNICAL VERIFICATION – BIOEQUIVALENCE DATA

Critical Information		Yes (Y)	No (N)
1	Are the following components of the biostudy included:		
1a	The protocol and report?		
1b	Was the reference product/ comparator used for the BE studies acceptable?		
1c	Has the applicant submitted the BTIF in MS Word format in the electronic submission?		

2	If a BCS or an additional strength biowaiver is requested, are the following included:		
2a	a motivation and justification? (i.e. BCS class I and III APIs or line extension)		
2b	A full report in accordance with the report format described in the Dissolution Guideline with the appropriate data comparing the test and reference products**?**		
2c	Was the reference product/ comparator used for the BCS BW studies acceptable?		
2d	Has the applicant submitted the BW form in MS word format in the electronic submission?		

[i] Acceptable reference products are those procured from countries with stringent regulatory authorities (PICs countries that joined before 2008 and those SRA that NMRC aligns itself with) and/ or the reference product is already registered with NMRC**.**

Comments:

Screening outcome:

Approved ☐ means the applicant has to pay the application fee for the next evaluation process

Rejected ☐ means the applicant has to come and collect his/her application dossier and pay screening fees if he/she wishes to resubmit the same application again dossier.

Screened by: <full name of screener and signature> *Submitted by: <full name and signature>*

Date screened:

Approved by: ……..

Mr. Johannes #Gaeseb

Registrar of Medicines