MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

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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 South African Regulatory Authority.

Usually a separate application for each strength and pharmaceutical form is required.

MRF1		CTD		eCTD	

A ADMINISTRATIVE

A.1 SCREENING

Product and dossier information (C = Critical)			
1	Applicant	**C**	<LICENSED NAME>
2	Product reference number		
3	Product proprietary name	**C**	<Name, strength; pharmaceutical form>
4	Screening fee included (cheque or proof of payment, submitted in a separate envelope, with copy of the covering letter)	**C**	Y ☐ N ☐
5	Date of covering letter*		
6	Date of receipt		<date submitted>
7	Box size (A4 box)*	**C**	Y ☐ N ☐
8	Number of boxes*		<No.>
9	Are the boxes clearly labelled on the side to specify the number and content of each box, e.g. Modules/Parts, sample, covering letter (MRF1), cheque or proof of payment and product identification code / product name?*		Y ☐ N ☐

* Paper submissions

Product and dossier information (C = Critical)				
10	Does a red sticker indicate the screening phase? †		Y ☐	N ☐
11	Is the dossier correctly bound? (No lever arch files, no ring binders, 4 cm thick but not over-full for the binder used) †	**C**	Y ☐	N ☐
12	Have dividers been included in the paper submission?†	**C**	Y ☐	N ☐
13	Is a sample included in an envelope? (screening phase)	**C**	Y ☐	N ☐
14	Are samples provided for all pack types?		Y ☐	N ☐
15	Is the approval letter for “fast track” status included if relevant?		Y ☐	N ☐
16	Is Module 1.2.1(c) / PART 1A signed by the authorised pharmacist, and dated?	**C**	Y ☐	N ☐
17	Are Modules / PARTs 1-5 included?	**C**	Y ☐	N ☐

NOTES:

1. *The questions marked **C** are regarded as critical for acceptance of the application.*
2. *Return the application to the applicant if any critical issues are non-compliant.*

† Paper submissions

A.2 POST-SCREENING FOR PAPER SUBMISSIONS

Product and dossier information (C = Critical)			
1	Applicant	**C**	<LICENSED NAME>
2	Product reference number		
3	Product proprietary name	**C**	<Name, strength; pharmaceutical form>
4	Application fee included (cheque or proof of payment, submitted in a separate envelope, with copy of the covering letter)	**C**	Y ☐ N ☐
5	Date of covering letter‡		
6	Date of receipt		<date submitted>
7	Box size (A4 box)‡	**C**	Y ☐ N ☐
8	Number of boxes‡		<No.>
9	Are the boxes clearly labelled on the side to specify the number and content of each box, e.g. set numbers, Modules/Parts, covering letter (MRF1), cheque or proof of payment and product identification code / product name?‡	**C**	Y ☐ N ☐
10	Does a green sticker indicate the post-screening phase?‡		Y ☐ N ☐
11	Is the dossier correctly bound? (No lever arch files, no ring binders, 4 cm thick but not over-full for the binder used)‡	**C**	Y ☐ N ☐
12	Is Module 1.2.1(c) / PART 1A signed by the authorised pharmacist, and dated?	**C**	Y ☐ N ☐

NOTES:

1. *The questions marked **C** are regarded as critical for acceptance of the application.*
2. *Return the application to the applicant if any critical issues are non-compliant.*

‡ Paper submissions

B TECHNICAL VERIFICATION - PHARMACEUTICAL QUALITY ASSESSOR

Critical Pharmaceutical Quality Information		Yes (Y)	No (N)
1	Stability data on the active pharmaceutical ingredient (API):		
1a	NCE: At least 12 months long-term and 6 months accelerated?[§]		
1b	Well-known: At least 6 months long-term and 3 months accelerated OR Supporting literature[§]		
2	Is Module 3.2.S/ PART 3A for each manufacturer of API included?		
2a	Where more than one manufacturer of the API (not the same parent company) is used, are comparative chemical and physical data in tabular format included to demonstrate equivalence?		
2b	Has the comparative chemical and physical data been generated by the same testing laboratory (laboratory stated) under the same conditions?		
2c	Where more than one site of the same parent company is used and an identical method of synthesis is used at these sites has a statement to this effect been included?		
2d	Where more than one site is used for manufacturing of the API, have valid CoAs issued by each site for at least two batches within the retest period at the time of submission of the application been included?		
3	Stability data on the pharmaceutical product (FPP):		
3a	NCE: At least 12 months long-term and 6 months accelerated?		
3b	Generics: At least 9 months long-term and 3 months accelerated?		
3c	Is a tabulated summary of the batches, i.e. sizes, numbers, type, packaging material, and conditions and period of testing included for each manufacturer?		
3d	Are details of the API source, container, batch number, batch size, date of manufacture of the batch, and storage conditions reflected in Module 3.2.P.8.1 or Module 3.2.P.8.3/ PART 3G?		
3e	Have stability data been derived with API sourced from the manufacturer identified in Module 3.2.S.2.1/ PART 3A(b)?		
3f	If the answer is NO to question 3e, are pharmaceutical equivalence data of the API sources included in Module 3.2.R.3/ PART 3A(c)?		
3g	Have stability data been derived from the product packed in packaging material(s) detailed in Module 3.2.P.7/ PART 3D?		
3h	Are validation data for the stability testing assay method (if not pharmacopoeial and/or different to that in Module 3.2.P.5.2 /PART 3F included?		
3i	Are validation data included for the method(s) used to test degradation products		

[§] Storage conditions as defined in current official Stability Guideline

C TECHNICAL VERIFICATION - BIOEQUIVALENCE DATA

Critical Information		Yes (Y)	No (N)
1	Is/are the fasting and/or fed bioequivalence study(ies) in compliance with the Biostudies guideline requirements for the design and conduct of studies for immediate or modified release products, as applicable?		
2	Are the following components of the biostudy included:		
2a	Date and place of study?		
2b	The protocol?		
2c	Evidence of ethical approval?		
2d	Assay validation plus representative chromatograms from analytical runs for 20 % of all subjects (or for a minimum of 4 subjects) whichever is the greater, including chromatograms for the associated standards and quality control samples, and do they comply with the requirements for legibility?		
2e	Investigator's *curriculum vitae*?		
2f	Quality assurance statement?		
3	Have all the individual patient Case Report Forms (CRFs) and individual patient line listings been removed?		
4	Has the country of procurement of the reference product and name and address of the relevant applicant been stated?		
5	Was the reference product procured in a country with which the MCC aligns itself?		
6	Is the biostudy reference product strength within the MCC approved package insert dose range?		
7	If relevant, has a full report on comparative data to demonstrate equivalence of the foreign reference product to the S.A. registered innovator product submitted?		
8	If a biowaiver is requested for additional strengths of the product:		
8a	Are the additional strengths proportionally formulated?		
8b	Were the additional strengths manufactured by the same manufacturer, at the same site, with API(s) sourced from the same manufacturer?		
8c	Have appropriate quantitative methods, e.g. dissolution data in three media in accordance with the Dissolution guideline, been used to confirm similarity and is a full report in accordance with the report format described in the Dissolution Guideline with the appropriate data included with this application [e.g. similarity (f2) factor]?		
9	If a BCS biowaiver is requested, are the following included:		
9a	a motivation and justification?		
9b	a full report in accordance with the report format described in the Dissolution Guideline with the appropriate data comparing the test and reference products in the three dissolution media, **pH's 1,2; 4,5** and **6,8?**		

D TECHNICAL VERIFICATION - PRE-CLINICAL AND CLINICAL INFORMATION

Critical Information		Yes (Y)	No (N)
1	Are the proposed package insert (PI) and the proposed patient information leaflet (PIL) included in Module 1.3.1 / PART 1C?		
2	Is the information in the proposed PI cross-referenced to the locally submitted supporting evidence?		
3	Has the information in the proposed PIL been cross-referenced to the proposed PI?		
4	Has the information in Modules 2.4, 2.5, 2.6 and 2.7 been included?		
5	Has the information of Modules 4 and 5 of the ZA CTD been included and is the proposed PI cross-referenced to this information?		
6	Are the references referred to in the proposed PI included?		
7	Are the cross-references complete, accurate and properly indexed?		
8	Have all the raw data (individual patient data and line listings) been removed?		

NOTES:

1. *In case of any one or more answers being "No", refer to MCC section coordinator.*
2. *Unless otherwise decided, the assessment should not commence if these matters have not been (adequately) addressed. The final decision could be made at the P&A and/or CCC meeting.*