QMS N°: ODG/FMT/049

Rev. Nº: 0

Effective date: 02/02/2021 Ref. Doc.: QMS /MAN /002



Rwanda Food and Drugs Authority

Nyarutarama Plaza KG 9 Avenue Email: info@rwandafda.gov.rw; website: www.rwandafda.gov.rw

MINUTES OF THE MEETING N°... /03/FDA/2021 FOR [Drugs and Health Technologies Assessment and Registration Division]

Date of Meeting 26/03/2021.

Venue of the meeting: WEBEX.

Attendance List (Hard copy to be attached on these minutes)

S/Nº	Names	Position
1.	Uworoheje Innocent	Veterinary Diagnostics and Medical Devices Registration
		Officer
2.	Munyaneza Uwitonze Janvier	Medicinal Cosmetics Registration Officer
3.	Nshimiyimana Philbert	Biological Products Registration Officer
4.	Karasanyi Geofrey	Veterinary Medicines Registration and Variations Assessment Officer
5.	Iradukunda Gad Patrick	Medicinal Cosmetics Registration Officer
6.	Ayinkamiye Honoré	FPP and API Assessment and Registration Officer
7.	Niyitegeka Leodomir	Medicinal Cosmetics Registration Officer
8.	Uwamariya Pacifique	Director of Cosmetics and household Chemicals
9.	Irasabwa Clarisse	DM of Drugs and Health Technologies Assessment and Registration
10.	Munyangaju Edouard	Division Manager /Drugs and Food inspection and compliance
11.	Frederic Muhoza	Clinical Trial Specialist
12.	Evariste Byomuhange	Pharmacist in Charge of MIS
13.	Tite Uwambajineza	Human Medicine Lab Officer

Items on the agenda

Peer Review Meeting for Validation of Assessed Products Dossiers



2

Page 1 of 10

QMS Nº: ODG/FMT/049

Rev. Nº: 0

Effective date: 02/02/2021 Ref. Doc.: QMS /MAN /002

Opening and/or remarks of the meeting

The Meeting has started at 10:30 AM with the opening remarks given by the DM of Drugs and Health Technologies Assessment and Registration. She started by thanking the whole participants to peer review meeting to validate both assessed hand sanitizers, cosmetic and medicinal product dossiers. The Division manager highlighted that 6 PDs including and 1 human medicinal product, 1 Cosmetic product and 4 hand sanitizers are to be validated with an aim find out whether they qualify to be granted marketing authorization in Rwanda.



1

Page 2 of 10





The Meeting Proceedings

		de)	2.1. Experience hand sanitizer gel (Ethanol and hydrogen peroxide)	2.1. Experience hand sanitizer g
				2. HAND SANITIZERS
Done	Honoré	It was also concluded that: The product is recommended for approval. If an applicant has applied and paid for GMP inspection by Rwanda FDA, once his/her products fulfils all other requirements and remains with query on GMP inspection, the product will be approved for registration with the condition that the inspection will be carried out later. For Products applied for through CRP, the product will be registered and the inspection will be registered out later. Moreover, after Rwanda FDA carried first GMP inspection, it will be now possible that for the next time, a desk review can be enough.	It was observed that all queries have been resolved by the applicant though on the issue of GMP certificate, the applicant indicated that (NADFC Indonesia) is currently undergoing changes of representative people, so the original GMP certificate in appropriate format was not issued yet, but a valid GMP certificate for administration purposes in Indonesia was provided and a proof of application for GMP inspection by Rwanda FDA was provided.	It was presented that SANTOCYN® Injection with reference number 1088/2020 and manufactured by PT Sanbe Farma had queries related to API Specifications from FPP manufacturer not dated and signed, API analytical procedures without reference, version number and date, labelling information, expired GMP Certificate, unsigned and non-dated FPP Specifications, FPP Analytical procedures with no reference, version number and date. All of the raised queries have been resolved by the applicant
Timelines	Responsible for person for implementation	Resolutions/ recommendation	Observation	Discussion
		kytocin Solution for Injection]	UCT: SANTOCYN® Injection [O	1. HUMAN MEDICINAL PRODUCT: SANTOCYN® Injection [Oxytocin Solution for Injection]

Effective date: 02/02/2021 Ref. Doc.: QMS /MAN /002



	recommended for registration.	the product has been	issued by Rwanda FDA. Hence	valid manufacturing License was	longer valid but as for now, the	manufacturing License was no	Then after it was found that the	and given conditional registration.	The product dossier was assessed	provided by the applicant.	satisfactory responses have been appearance, PH, Alcohol content	stability studies. To these later,	critical parameters as well as the	related to in-process control and	L'EXPERIENCE had queries	LABORATOIRE	manufactured by	number 6526/2020 and which is	hand sanitizer gel with reference	It was presented that Experience It was observed that all raised It was concluded that:
			Rwanda Food	K VV A	TO TATA		25	hand sanitizer.	a requirement in standards for	and bacteridal efficacy yet this is	appearance, PH, Alcohol content	indicating parameters like	not used to mention stability	and the local manufacturers are	concentration reduces with time	was observed that alcohol	submitted stability study data, it	the applicant. However, in the	queries have been resolved by	It was observed that all raised
licence has one year of validity yet registration certificate has 5	✓ Since the manufacturing	provided	should continuously be	prepare their PD for application	manufacturers on how to	✓ Further guidance for local	information	shelf-life in product labeling	recommended to add the in use	✓ The manufacturers should be	tested.	indicating parameters to be	stability studies and stability	hand sanitizers clearly clarify	guidelines on registration of	whether Rwanda FDA	✓ Director Pacifique will check	for approval.	√ The product is recommended	It was concluded that:
=																				Leodomir

Effective date: 02/02/2021 Ref. Doc.: QMS /MAN /002





		١.	and bacteridal efficacy yet this is	stability statios. To those meet,
		stability studies and stability	appearance, PH, Alcohol content	stability studies. To these later.
		hand sanitizers clearly clarify	indicating parameters like	critical parameters as well as the
		on registrati	not used to mention stability	related to in-process control and
		guidelines on registration of	and the local manufacturers are	L'EXPERIENCE had queries
		whether Rwanda FDA	concentration reduces with time	LABORATOIRE
		✓ Director Pacifique will check	was observed that alcohol	and which is manufactured by
		ior approvai.	submitted stability study data, it	with reference number 8264/2020
			the applicant. However, in the	hydroalcoholic antibacterial
		✓ The product is recommended	queries have been resolved by	hand sanitizer solution
Done	Leodomir	It was concluded that:	It was observed that all raised	It was presented that Experience
	٣	al (Ethanol and hydrogen peroxide)	lution hydroalcoholic antibacteri:	2.2. Experience hand sanitizer solution hydroalcoholic antibacterial (Ethanol and hydrogen
		withdrawn from the market.		
		it has been registered with is		
		conform with quality standards		
		products which does not	e e	
		invested in PMS so that any		
		✓ Lastly, much effort should be		
		terminated.		
		not renewed, the MA is also		
		once a manufacturing licence is		
		inspection department so that	6	
		work closely with those from		
		the department of registration to		
		years of validity, this requires		
		المناطقة الم		

Page **5** of **10**

QMS N°: ODG/FMT/049 Rev. N°: 0 Effective date: 02/02/2021 Ref. Doc.: QMS /MAN /002

satisfactory responses have been	a requirement in standards for	indicating parameters to be	
provided by the applicant.	hand sanitizer.		
The product dossier was assessed	nama samezer.	tested.	
and given approval for registration		✓ The manufacturers should be	
with recommendation. Then after	650	adding the in use shelf-life in	
it was found that the	1	product labeling information	
manufacturing License was no longer valid but as for now, the		✓ Further guidance for local	
valid manufacturing License was	100	manufacturers on how to prepare	
issued by Rwanda FDA. Hence		their PD for application should	
the product has been recommended for registration.		continuously be provided	
l l l l l l l l l l l l l l l l l l l		✓ Since the manufacturing	
		licence has one year of validity	
	Marie Contraction	yet registration certificate has 5	
	311	years of validity, this requires	
	-311	the department of registration to	
		work closely with those from	
	TOTATAN	inspection department so that	
	KWAN	once a manufacturing licence is	
	Rwanda Food	not renewed, the MA is also	
	manda 1000	terminated.	
		✓ Lastly, much effort should be	
		invested in PMS so that any	
		products which does not	

Page 6 of 10



		ioi appiovai.	queixs imite occii iesoirea oj	sanitizer gel with reference
		for anneoual	reference oneries have been resolved by for approval	-
Done	Patrick	recommended	It was observed that the raised	It was presented that Toplife hand It was observed that the raised The product is
		rogen peroxide)	R Liquid (Ethanol 80% v/v Hyd	2.4. TOPLIFE HAND SANITIZER Liquid (Ethanol 80% v/v Hydrogen peroxide)
				were judged as minor.
				been well resolved whereas others
				stability study. Some queries have
			should be enforced.	bureau of Standard web and
			manufacturing companies	which assessor traced at Kenya
			Therefore, teaching local	report with missing parameters
			local manufacturing companies.	PH and Alcohol content, analysis
			registration when compared to	description, COA, Appearance,
			preparing PD to submit for	manufacturing flow chat and its
			have advanced knowledge in	GMP, material safety datasheet,
			observed that foreign companies	LIMITED had queries related to observed that foreign companies
			queries by assessor. It was also	manufactured by TOP LIVO queries by assessor. It was also
			the applicant or judged as minor	number 6556/2020 and which is
		for approval.	queries have been resolved by for approval.	sanitizer gel with reference
	Patrick	The product is recommended	It was observed that the raised	It was presented that Toplife hand It was observed that the raised
		gen peroxide)	R GEL (Ethanol 80% v/v Hydro	2.3. TOPLIFE HAND SANITIZER GEL (Ethanol 80% v/v Hydrogen peroxide)
		withdrawn from the market.		
		has been registered with is		
		conform with quality standards it		

QMS N°: ODG/FMT/049
Rev. N°: 0
Effective date: 02/02/2021
Ref. Doc.: QMS /MAN /002

QMS N°: ODG/FMT/049
Rev. N°: 0
Effective date: 02/02/2021
Ref. Doc.: QMS /MAN /002



INTED had queries related to GMP, material safety datasheet, manufacturing flow chat and its description, COA, Appearance, PH and Alcohol content, analysis report with missing parameters which assessor traced at Kenya bureau of Standard web and stability study. Some queries have been well resolved whereas others were judged as minor.	queries by assessor. It was also observed that foreign companies have advanced knowledge in preparing PD to submit for registration when compared to local manufacturing companies. Therefore, teaching local manufacturing companies should be enforced.
were judged as minor. 3. DERMOL EMOLLIENT CRE.	
	M (White soft paraffin 14.5%W/W, Liquid paraffin 12.6% W/W
It was presented that	araffin 1
was presented that MOLLIENT with reference	
was presented that MOLLIENT with reference imber 5773/2020 and which is	
was presented that MOLLIENT with reference imber 5773/2020 and which is anufactured by BIODEAL	
was presented that MOLLIENT with reference imber 5773/2020 and which is anufactured by BIODEAL ABORATORIES LIMITED had	
was presented that MOLLIENT with reference Imber 5773/2020 and which is anufactured by BIODEAL ABORATORIES LIMITED had Ieries related to containing	
vas presented that LIENT with reference 5773/2020 and which is ctured by BIODEAL RATORIES LIMITED had related to containing ted ingredient(Petrolatum),	



been satisfactorily resolved. been satisfactorily resolved. the time of first application) for cosmetic product that has changed to 500USD after current revision of regulations related to regulatory services tariff/fees and fines by Rwanda FDA. This means the Authority owes the applicant a sum of 250USD.	the time of first application) for cosmetic product that has changed to 500USD after current revision of regulations related to regulatory services tariff/fees and fines by Rwanda FDA. This means the Authority owes the applicant a sum of 250USD.	been satisfactorily resolved.	COA. All queries hav
		product instead of 1000USD (at	application fees for a medicinal
		#	

RWANDA FDA

QMS N*: ODG/FMT/049
Rev. N*: 0
Effective date: 02/02/2021
Ref. Doc.: QMS /MAN /002

QMS N°: ODG/FMT/049 Rev. N°: 0 Effective date: 02/02/2021

Ref. Doc.: QMS/MAN/002

Names, and signature and/or Names and signature institution stamp Chair of the Clarisse IRASABWA Philbert SHIMIYIMANA meeting Rapporteur

The meeting has ended at: 1h15 PM

End of Minutes

Page 10 of 10

QMS Nº: ODG/FMT/049

Rev. Nº: 0

Effective date: 02/02/2021 Ref. Doc.: QMS /MAN /002



Rwanda Food and Drugs Authority

Nyarutarama Plaza KG 9 Avenue Email: info@rwandafda.gov.rw; website: www.rwandafda.gov.rw

MINUTES OF THE MEETING N°... /03/FDA/2021 FOR [Drugs and Health Technologies Assessment and Registration Division]

Date of Meeting 26/03/2021.

Venue of the meeting: WEBEX.

Attendance List

S/Nº	Names	Position	Signature
1.	Uworoheje Innocent	Veterinary Diagnostics and Medical Devices	
		Registration Officer	410
2.	Munyaneza Uwitonze	Medicinal Cosmetics Registration Officer	
	Janvier		printer
3.	Nshimiyimana Philbert	Biological Products Registration Officer	(him)
4.	Karasanyi Geofrey	Veterinary Medicines Registration and Variations	11/<7
		Assessment Officer	- This
5.	Iradukunda Gad Patrick	Medicinal Cosmetics Registration Officer	4A
6.	Ayinkamiye Honoré	FPP and API Assessment and Registration Officer	James'
7.	Niyitegeka Leodomir	Medicinal Cosmetics Registration Officer	Vm Jew
8.	Uwamariya Pacifique	Director of Cosmetics and household Chemicals	1
9.	Irasabwa Clarisse	DM of Drugs and Health Technologies Assessment and	/ / /
		Registration	June have
10.	Munyangaju Edouard	Division Manager /Drugs and Food inspection and	
		compliance	· ·
11.	Frederic Muhoza	Clinical Trial Specialist	Alleson
12.	Evariste Byomuhange	Pharmacist in Charge of MIS	
13.	Tite Uwambajimana	Human Medicine Lab Officer	(1)

Items on the agenda

Peer Review Meeting for Validation of Assessed Products Dossiers

Page 1 of 10