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 No: ..../...../FDA/2021 FOR PEER REVIEW

**Date of Meeting: 17/06/2021** 

Venue of the meeting: Virtual

## Attendance List (Hard copy to be by a hand-signed and attached on these minutes)

S/Nº	Names	Position
1.	Dr.Eric NYIRIMIGABO	Division Manager of Human Medicine and Devices Assessment and Registration
2.	Dr.Rosine MANISHIMWE	Division Manager of Veterinary Medicine Devices and Assessment and Registration
3.	Dr.Janvier MUKIZA	Division Manager of Cosmetics and Household Chemicals Assessment and Registration
4.	Dr.Doreen INGABIRE	Veterinary Medicines in Vitro Diagnostics and Medical Devices Registration Analyst
5.	Dr.Richard HABIMANA	Vaccines and Biosimilar Registration Analyst
6.	Clarisse IRASABWA	Finished and Active Pharmaceutical Products Registration Analyst
7.	Deo GASANA	Finished and Active Pharmaceutical Products Registration Analyst
8.	Tite UWAMBAJINEZA	Radiopharmaceuticals and Radiotherapy Products Assessment and Registration Analyst
9.	Dr.Emil Ivan MWIKARAGO	Diagnostics and Medical Devices Registration Analyst
10.	Jurdas SEZIRAHIGA	Public Health and Laboratory Chemicals Registration Analyst
11.	Honore AYINKAMIYE	Ag Finished and Active Pharmaceutical Products Registration Specialist
12.	Marie Ange ISINGIZWE	Ag Finished and Active Pharmaceutical Products Registration Specialist
13.	Nadine NIYOMAHORO	Ag Finished and Active Pharmaceutical Products Registration Specialist
14.	Anitha TUYISHIME	Ag Herbal Medicines Assessment and Registration Specialist



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15.	Ruth MUHONGERWA	Ag Herbal Medicines Assessment and Registration Specialist		
16.	Dr. Placide MUHAYIMANA	Placide MUHAYIMANA Ag Diagnostics and Medical Devices Registration Specialist		
17.	Serge SHYIRAMBERE	Ag Vaccines and Biosimilar Registration Specialist		
18.	Damascene DUSABIMANA	Ag Vaccines and Biosimilar Registration Specialist		
19.	Olivier MURERAMANZI	Ag Biological Products Registration Specialist		
20.	Diane ITETERE	Ag Biological Product Registration Specialist		
21.	Geoffrey KARASANYI	Ag Veterinary Medicines Registration and Variation Assessment Specialist		
22.	Nadia UWERA	Ag Veterinary Medicines Registration and Variation Assessment Specialist		
23.	Felix TUYISENGE	AgVeterinary in vitro Diagnostics and Medical Devices Registration Specialist		
24.	Patrick GAD IRADUKUNDA	Ag Cosmetics Registration Specialist		
25.	Leodomir NIYITEGEKA	Ag Cosmetics Registration Specialist		
26.	Gentille MASENGESHO	Ag Public Health and Laboratory Chemicals Registration Specialist		
27.	Innocent UWOROHEJE	Ag Veterinary Medicines Testing Officer		
28.	Jean Pierre NSANZIMFURA	Ag Cosmetic Testing Officer		
29.	Janvier MUNYANEZA	Ag Pesticides Testing Officer		
30.	Jackson KARARA	Ag Food and Drugs Port of Entry Inspection Specialist		
31.	Jeremie NTEZIYAREMYE	Industrial and Market Specialist		

#### Item on the agenda

Presenting final dossier assessment reports of Human medicines products, Antiseptics and disinfectants products to the Peer review committee for approval (27 Products).

## Opening and/or remarks of the meeting

The meeting started at 03:05 pm with the opening remarks of the Division Manager of Human Medicine and Devices Assessment and Registration, Dr. Eric Nyirimigabo who introduced the participants and presented the agenda of the meeting.



Discussion	Observation	Resolutions/ recommendation	Presenter	Timelines
FASTUM GEL with reference number 0863/2019 and manufactured by MENARINI Industry Farmaceutiche riunite S.R.I was presented and had queries, where the applicant has well responded to all queries raised in addition, have applied for GMP inspection and paid the prescribed fees.	FASTUM GEL is a gel of mucilaginous consistent, colorless or almost transparent, with an aromatic odour.  The initial application was assessed through full assessment with the outcome of "additional data requested" for the first round. It was observed that all queries have been resolved by the applicant.	Based on the information from the assessment report, it has been agreed upon that the safety and efficacy were supported and the product was recommended for registration.	Jean Pierre Nsanzimfura.	Done
EASCOF EXPECTORANT manufactured by Cachet Pharmaceuticals PVT LTD was presented and responded well to the queries, in addition, have applied for GMP inspection and paid the prescribed fees.	EASCOF EXPECTORANT is an Orange-yellow colour clear liquid having sweet taste and pleasant flavour manufactured. The initial application was assessed through full assessment with the outcome of "additional data requested" for the first round. It was observed that all queries have been resolved by the applicant.	Based on the information from the assessment report, it has been agreed upon that the safety and efficacy were supported and the product was recommended for registration.	Jean Pierre Nsanzimfura.	Done
SOMAZINA 1000MG ORAL SOLUTION with reference number 1833/2018 &2235/2019 manufactured by FERRER INTERNATIONAL S.A/SPAIN was presented and responded well to	SOMAZINA 1000MG ORAL SOLUTION is an oral solution manufactured by Ferrer Internacional.S. A. The initial application has been assessed	Somazina 1000mg oral solution has fulfilled the registration requirement and was recommended for registration	Jean Pierre Nsanzimfura	Done





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

the queries. Furthermore, an application for GMP inspection was done and the prescribed fees were paid.	through full assessment procedure with the outcome of additional data at the first round which was fully responded to support the quality, safety and efficacy of the product.			
GAMALATE (TABLETS) with reference number 1830/2018 & 2231/2019 and manufactured by FERRER INTERNATIONAL S.A/SPAIN was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	blue sugar-coated tablet. The initial application has been assessed through full assessment procedure with the outcome of additional data at the first round which were fully responded to support the quality, safety and efficacy of the product.	Gamalate Tablets has fulfilled the registration requirement and was recommended for registration	Jean Pierre Nsanzimfura	Done
GAMALATE B6 ORAL SOLUTION with reference number 1835/2018 &2232 and manufactured by FERRER INTERNATIONAL S.A/SPAIN was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	GAMALATE B6 ORAL SOLUTION is a viscous orange liquid with characteristics of odour and taste manufactured by Ferrer Internacional S.A. The initial application has been assessed through full assessment procedure with the outcome of additional data at the first round which were fully responded to support the quality, safety and efficacy of the product.	Gamalate Syrup has fulfilled the registration requirement and was recommended for registration.	Jean Pierre Nsanzimfura	Done

8

BEVAAS-100 with reference	BEVAAS-100 is a clear and	The product is recommended	Serge	Done
number 677/2018 and	pale yellow to colorless liquid	for registration with condition	Shyirambere	
manufactured by <b>HETERO</b>	free from particles that can be	i.e. the certificate will be issued		
BIOPHARMA/INDIA. The	observed by visual inspection	after payment of 15USD.		
applicant sufficiently responded to	manufactured by Hetero			
the queries regarding the	Biopharma Limited. The			
submission of openable and	product fulfilled other			
readable documents of process	requirements and it was			
validation protocol and report.	recommended that liaise with			
The applicant was also requested	the office of finance to			
to apply for GMP inspection and	communicate to the applicant	in the second se	la.	
pay the prescribed fees, however,	about the remaining amount of			
it was noted that a payment fee	15USD on GMP inspection fees.			
made was 4985USD implying				
15USD less to the presumed				
payment.				
				•
BEVAAS-400 with reference	BEVAAS-400 is a clear and	The product is recommended	Serge	Done
number 676/2018 and	pale yellow to colorless liquid	for registration with condition	Shyirambere	
manufactured by HETERO	free from particles that can be	i.e. the certificate will be issued after payment of 15USD.		
BIOPHARMA/INDIA was	observed by visual inspection	after payment of 1505b.		
presented and responded well to	manufactured by Hetero	DATDA		
the queries. Furthermore, an	Biopharma Limited. The query	and Democ Authority		
application for GMP inspection	related to the application for	mu rangs Anthorny		
was done and the prescribed fees	registering BEVAAS-100 were			
was paid. The product also shares	sufficiently responded to and			
the query on GMP fees with other	liaise with the office of finance			
products from HETERO	to communicate to the applicant			
BIOPHARMA/INDIA	about the remaining amount of			

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

SEVLAREN 400 with reference number 13973/2018 and manufactured by Stanford Laboratories Private Limited was presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applicant responded well to the queries included a query on whereby the applicant responded well to the the payment fee made was 4985USD.  SEVLAREN 400 with reference number 13973/2018 and off white circular shaped for registration on condition.  SEVLAREN 400 is a white to off white circular shaped for registration on condition.  SEVLAREN 400 with reference number 13973/2018 and off white circular shaped for registration on condition.  SEVLAREN 400 with reference number 13973/2018 and off white circular shaped for registration on condition.  Stanford Laboratorics Private Limited that has sufficiently satisfied the requirements to justify SEQ.  WEPOT) is White to off White condition i.e. the certificate will be harat Serum & Vaccines Limited was presented and responded well to the queries included a query on the GMP inspection application whereby the applicant responded to the queries related to quality and safety.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees was recommended.					
SEVLAREN 400 with reference number 13973/2018 and manufactured by Stanford Laboratories Private Limited. was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.  LUPRODEX 3.5MG (DEPOT) with reference number 1124/2019 and manufactured by Bharat Serum & Vaccines Limited was presented and responded well to the queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  SEVLAREN 400 is a white to off white circular shaped for registration on condition.  The product was recommended for registration on condition.  The product was recommended for registration on condition.  The product was recommended of registration on condition.  The product was recommended for registration on condition.  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Done Shyirambere  Luprodex 3.5MG (DEPOT) with the condition i.e. the certificate will be issued after payment of 15USD.  LUPRODEX 3.5MG (DEPOT) application for Luprodex was recommended for registration on condition.  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Luprodex 4.5 Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Shyirambere  Serge Shyirambere  Serge Shyirambere  Shyirambere  Serge Shyirambere  Serge Shyirambere  Shyirambere  Serge Shyirambere  Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Shyirambere  Serge Shyirambere  Serge Shyirambere  Serge Shyirambere  Shyirambere  Serge Sh		15USD on GMP inspection fees			
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Laboratories Private Limited. was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.  LUPRODEX 3.5MG (DEPOT) with reference number 1124/2019 and manufactured by Bharat Serum & Vaccines Limited was presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	number 13973/2018 and	off white circular shaped	for registration on condition.	Shyirambere	-
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to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.  LUPRODEX 3.5MG (DEPOT) with reference number 1124/2019 and manufactured by Bharat Serum & Vaccines Limited was presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  Limited that has sufficiently satisfied the requirements to justify SEQ.  LUPRODEX 3.5MG (DEPOT) is White to off White Lyophilized Powder for Injection manufactured by Bharat Serum&Vaccines Limited Application for LUPRODEX 3.5MG (DEPOT) serum & Done Shyirambere of 15USD.  Limited that has sufficiently satisfied the requirements to justify SEQ.  The product was recommended for registration with the condition i.e. the certificate will be issued after payment of 15USD.  Serge Shyirambere of 15USD.  Limited that has sufficiently satisfied the requirements to justify SEQ.  The product was recommended for registration with the condition i.e. the certificate will be issued after payment of 15USD.  Limited that has sufficiently satisfied the requirements to justify SEQ.  The product was recommended for registration with the condition i.e. the certificate will be issued after payment of 15USD.  Serge Shyirambere Shyirambere value is sufficiently after the condition i.e. the certificate will be issued after payment of 15USD.  Limited that has sufficiently satisfied the requirements to distribute the officiently registration with the condition i.e. the certificate will be issued after payment of 15USD.  Limited that has sufficiently registration with the condition i.e. the certificate will be issued after payment of 15USD.	Laboratories Private Limited.	both sides manufactured by			
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LUPRODEX 3.5MG (DEPOT) with reference number 1124/2019 (DEPOT) is White to off White and manufactured by Bharat Serum & Vaccines Limited was presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  LUPRODEX 3.5MG (DEPOT) is White to off White Condition i.e. the certificate will be issued after payment of 15USD.  Serge Shyirambere Condition i.e. the certificate will be issued after payment of 15USD.  Limited. Application for LUPRODEX 3.5MG (DEPOT) sufficiently responded to the queries related to quality and safety.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	application for GMP inspection	satisfied the requirements to			
LUPRODEX 3.5MG (DEPOT) with reference number 1124/2019 and manufactured by Bharat Serum & Vaccines Limited was presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  LUPRODEX 3.5MG (DEPOT) is White to off White Lyophilized Powder for Injection manufactured by Bharat Serum&Vaccines Limited. Application for LUPRODEX 3.5MG (DEPOT) sufficiently responded to the queries related to quality and safety.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	was done and the prescribed fees	justify SEQ.			
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and manufactured by Bharat Serum & Vaccines Limited was presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applying however, it was noted that the payment fee made was 4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees  Lyophilized Powder for Injection i.e. the certificate will be issued after payment of 15USD.  Condition i.e. the certificate will be issued after payment of 15USD.	LUPRODEX 3.5MG (DEPOT)	LUPRODEX 3.5MG	The product was recommended	Serge	Done
Serum & Vaccines Limited was presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applying however, it was noted that the payment fee made was 4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	with reference number 1124/2019	(DEPOT) is White to off White		Shyirambere	
presented and responded well to the queries. Among the raised queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  Limited. Application for LUPRODEX 3.5MG (DEPOT) sufficiently responded to the queries related to quality and safety.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	and manufactured by Bharat	Lyophilized Powder for	The state of the s	-	
the queries. Among the raised queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  Bharat Serum&Vaccines Limited. Application for LUPRODEX 3.5MG (DEPOT) sufficiently responded to the queries related to quality and safety.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	Serum & Vaccines Limited was	Injection manufactured by			
queries included a query on the GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	presented and responded well to	Bharat Serum&Vaccines	15080.		
GMP inspection application whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	the queries. Among the raised	Limited. Application for			
whereby the applicant responded by applying however, it was noted that the payment fee made was 4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	queries included a query on the	LUPRODEX 3.5MG (DEPOT)			
by applying however, it was noted that the payment fee made was 4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	GMP inspection application	sufficiently responded to the			
that the payment fee made was 4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	whereby the applicant responded	queries related to quality and	TO A TOTAL		
4985USD.  Liaise with the office of finance to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	by applying however, it was noted	safety.	IUATUA		
to communicate to the applicant about the missing amount of 15USD on GMP inspection fees	that the payment fee made was	D	and Description Association in the		
about the missing amount of 15USD on GMP inspection fees	4985USD.	Liaise with the office of finance	ind Drugs Authority		
15USD on GMP inspection fees		to communicate to the applicant			
•		about the missing amount of			
was recommended.		15USD on GMP inspection fees			
		was recommended.			

8

VASTEN-75 with reference	VASTEN-75 is a white to off-	The product was recommended	Serge	Done
number 3038/2019 and	white coloured, round-shaped,	for registration	Shyirambere	
manufactured by Lincoln	flat, uncoated tablet, break line			
Pharmaceuticals Limited, India	on one side and plain on other			
was presented and responded well	side manufactured by Lincoln	A 32)		
to the queries. Furthermore, an	Pharmaceuticals Limited, India.			
application for GMP inspection	The application complied with			
was done and the prescribed fees	safety, efficacy and quality	_ 30	9	
was paid.	requirements.			
	- W			
	Notice: The first assessment of			
	VASTEN-75 was done in			
	green color instead of red as			
	per presumed in the SOP. This			
	was an inte <mark>rnal</mark> arrangeme <mark>n</mark> t			
	for the new staffs to be	All de son (Other		
	familiarized with an			-
	assessment before getting			
	training on dossier			
	assessment. There are other			
	documents that have been	INA ENA		
	assessed in the same manner.	LUBEUR		
BCG VACCINES FREEZE	BCG VACCINES FREEZE	The product was recommended	Nadine	Done
<b>DRIED</b> with reference number	DRIED is manufactured by	for registration	Niyomahoro	
2988/2016 and manufactured by	Serum Institute, India.			
Serum Institute, India. The	The application for GMP has			
application was presented in the	been cleared.			
previous peer review meeting with				





QMS N : ODG/FM 1/049 Rev. N°: 0 Effective date: 02/02/2021

the remaining query of the				
application for GMP inspection.				
MEASLES VACCINE LIVE	MEASLES VACCINE LIVE	The product was recommended	Nadine	Done
ATTENUATED with reference	ATTENUATED, FREEZE	for registration	Niyomahoro	
number <b>8089/2016</b> and	DRIED is manufactured by			
manufactured by Serum	Serum Institute, India		*	
Institute, India. The application	The application for GMP has			
was presented in the previous peer	been cleared.			
review meeting with the				
remaining query of the application				
for GMP inspection.				
REPOITIN IU PFS with	REPOITIN IU PFS is	The product was recommended	Nadine	Done
reference number 21494/2015 &	manufactured by Serum	for registration	Niyomahoro	
4778/2019 and manufactured by	Institute, India	100		
Serum Institute, India. The	The application for GMP has	11//		
application was presented in the	been cleared.	All Carry ( ) The		
previous peer review meeting with				
the remaining query of the				
application for GMP inspection.	A Company of the Comp			
PAIDOFEBRIL ORAL	PAIDOFEBRIL ORAL	The product was recommended	Nadine	Done
SUSPENSION with reference	SUSPENSION is a white or	for registration	Niyomahoro	
number 14386/2018 and	almost white and homogeneous			
manufactured by Laboratorio	suspension with an orange odour	and Drugs Authority		
Aldo-Union, S.L was presented	after agitation manufactured by			
and responded well to the queries.	Laboratorio Aldo-Union, S. L.			
Furthermore, an application for	This was a second assessment of			
GMP inspection was done and the	the second round of additional data.			
prescribed fees was paid.	It has complied with registration			
	requirement including paying and			

	applying for GMP inspection at Rwanda FDA.			
TAPROS 3.75 with reference number 1172/2019 and manufactured by TAKEDA IRELAND LTD/IRELAND was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	TAPROS 3.75 is a human medicinal product manufactured by Takeda Pharmaceutical Company Limited.  The application passed the first and second assessment at the first round of additional data and has complied with registration requirement including paying and applying for GMP inspection at Rwanda FDA.	The product was recommended for registration	Geoffrey Karasanyi	Done
VIPIDOMET 12.5&1000 with reference number 0773/2019 and manufactured by TAKEDA IRELAND LTD/IRELAND was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	pale yellow, oblong, biconvex, film-coated tablet with "12.5/1000" debossed on one side and "322M" debossed on the other side manufactured by Takeda Pharmaceutical Company Limited.  Application of Vipidomet 12.5&1000 passed first and second assessment at the first round of additional data and has shown to comply with registration requirement including paying and applying for GMP inspection at Rwanda FDA.	The product was recommended for registration	Geoffrey Karasanyi	Done



QM5 N : ODG/FM1/049

Rev. Nº: 0

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

The	following	strengths	of
COV	ERAM were	presented:	

- COVERAM 10&10
- **COVERAM 10&5**
- **COVERAM 5&10**
- COVERAM 5&5

with the following respective reference number (3805/2016.A; 3805/2016.B; and 3805/2016.C manufactured by SERVIER (IRELAND) INDUSTRIES LTD was presented and responded well to the queries.

The application and proof of payment for GMP inspection by the Rwanda FDA was acknowledged.

COVERAM 10&10 is a white round-shaped tablet, engraved with "10/10" on one face and on the other face manufactured by Servier (Ireland) Industries LTD

COVERAM 10&5 is White Triangular—shaped tablet, engraved with"10/5" on one face and on the other face manufactured by Servier (Ireland) Industries LTD

coveram 5&10 is a white square-shaped tablet, engraved with "5/10" on one face and so on the other face manufactured by Servier (Ireland) Industries LTD

COVERAM 5&5 is a white rod-shaped tablet, engraved with 5/5" on one face and 50 on the other face manufactured by Servier (Ireland) Industries LTD

e I	The product was recommended for registration	Anitha Tuyishime	Done
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TRAMACETAL TABLETS	All COVERAM branded product mentioned above passed the first and second assessment at the second round of additional data and has shown to comply with the registration requirement.  TRAMACETAL TABLETS is	The product was recommended for registration but after the	Nadia Uwera	Done
with reference number 16065/2017 and manufactured by Cachet Pharmaceuticals Private Limited was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	a yellow coloured, oblong, biconvex, film-coated tablets with a breakline on one side manufactured by Cachet Pharmaceuticals Private Limited.  The application complied with safety, efficacy and quality requirements including the application for GMP inspection however the product sample was not submitted	submission of samples. Clarisse will follow up.		
VIPIDIA-25 with reference number 0774/2019 and manufactured by Takeda Ireland LTD was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	VIPIDIA-25 is a human medicinal product manufactured by Takeda Ireland LTD was assessed and the fact that all queries addressed were resolved.	The product was recommended for registration.	Jean Pierre Nsanzimfura	Done





Lamivudine/Tenofovir	Lamivudine/Tenofovir	The product was recommended	Honore	Done
disoproxil fumarate with	disoproxil fumarate 300	for registration.	Ayinkamiye	
reference number 8540/2020 and	mg/300 mg is a white, oblong			
manufactured by CELLTRION	shape, film-coated tablets			
PHARMA, INC./SOUTH	debossed with "C 0" on one side	× 32).		
KOREA was presented and	and plain on the other side			
responded well to the queries.	manufactured by Celltrion, Inc.			
Furthermore, an application for	The product was presented in			
GMP inspection was done and the	previous peer review where the		A	
prescribed fees was paid.	remaining query was to clarify			
	the difference in FPP			
	specification number, this has			
	been well clarified.			
FOLIC ACID TABLETS with	FOLIC ACID 5MG	The product was recommended	Dr. Placide	Done
reference number 2357/2019 and	TABLETS is a yellow, circular,	for registration on condition to	Muhayimana	
manufactured by	biconvex tablet plain on both	specify if the accepted container		
LABORATORY & ALLIED	sides manufactured by	will be used and samples will be		
LTD/KENYA was presented and	Laboratory & Allied Ltd.	submitted. Clarisse will follow		
responded well to the queries.	The application complied with	up.		
Furthermore, an application for	safety, efficacy and quality			
GMP inspection was done and the	requirements including the	TO A TIDA		
prescribed fees was paid.	application for GMP inspection	DATUA		
	however the product sample was	and December And Institute		
	not submitted and the proposed	tha Drugs Authority		
	pack size of 1000's in HDPE			
	container is not recommended.			
	It has been agreed to contact			1
	LTR for sample submission and			



	SEKROL SYRUP with reference number 3096/2019 and manufactured by Bilim Ilaç Sanayi ve Ticaret A.Ş was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	revision of the pack size to less than 90's in the HDPE container.  SEKROL SYRUP is a Clear, colourless, cherry odoured Syrup manufactured by Bilim Ilaç Sanayi ve Ticaret A.Ş. The application complied with safety, efficacy and quality requirements moreover, the applicant has applied for GMP inspection.	The product was recommended for registration.	Ruth Muhongerwa	Done
>	<b>EVOKE TABLETS</b> with reference number 2904/2019 and manufactured by Laboratory & Allied Ltd was presented and responded well to the queries. Furthermore, an application for GMP inspection was done and the prescribed fees was paid.	EVOKE TABLETS is a Blue diamond shaped biconvex film-coated tablets plain on both sides manufactured by Laboratory & Allied Ltd.  The application complied with safety, efficacy and quality requirements including the application for GMP inspection.	The product was recommended for registration.	Ruth Muhongerwa	Done
	PAUSE-500 TABLETS with reference number 1801/2019 and manufactured by Emcure Pharmaceuticals LTD was presented and responded well to the queries. Furthermore, an	PAUSE-500 TABLETS is White coloured circular biconvex film-coated tablet manufactured by Emcure Pharmaceuticals LTD.	The product was recommended for registration.	Dr.Eustache Musafiri	Done





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

application for GMP inspection	The application complied with		
was done and the prescribed fees	safety, efficacy and quality		
was paid.	requirements including the		
	application for GMP inspection.		
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QMS N°: ODG/FMT/049 Rev. N°: 0

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

Names and signature Names, and signature and/or institution stamp Chair of the Dr. Eric NYIRIMIGABO Marie Ange ISINGIZWE meeting Rapporteur

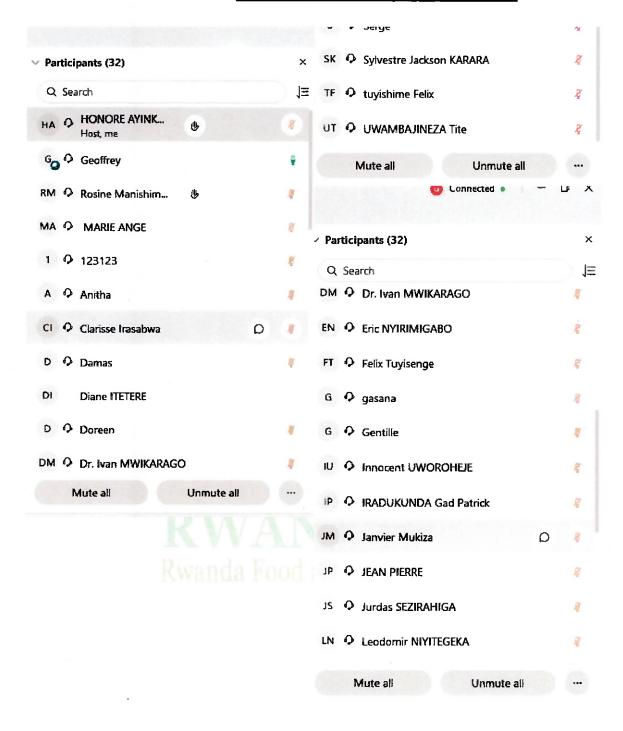
The meeting has ended on: 17th June 2021 at **08h10 PM** 

End of Minutes



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

### ANNEX: Screenshots of the participants on Webex





QMS N°: ODG/FMT/049 Rev. N°: 0

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





Page 17 of 17