

Issued by:

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Certificate of Analysis

Certificate Date	Certificate Number
17-DEC-2020	1000342498
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Material Description: COMBIVIR TABS 150/300MG 6X10
Material Number: 285274

Regulatory Statement:

I hereby certify that the below information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Batch No.	RY6U	Exp. Date	09 2022
Manf. Date	09 2020		

Importing Country:

Chile

Description	Specification	Results
Appearance	White to off-white capsule-shaped scored tablet, engraved with "GXFC3" on both tablet faces	Complies
Identity by HPLC	The retention times of the major peaks in the chromatogram of the sample correspond with those produced by the lamivudine and zidovudine reference standards	Complies
Uniformity of mass	Conforms to current Ph.Eur.	Complies
Lamivudine dissolution at 30 minutes	Conforms to current USP with a Q value of 80 %	>= 80
Zidovudine dissolution at 30 minutes	Conforms to current USP with a Q value of 80 %	>= 80
Lamivudine content by HPLC	142.5 - 157.5 mg/tab.	152,4
Lamivudine content by HPLC	95.0 - 105.0 %L.C.	101,6
Zidovudine content by HPLC	285.0 - 315.0 mg/tab.	298,5
Zidovudine content by HPLC	95.0 - 105.0 %L.C.	99,5

Qualified Person.

Approval is provided by Electronic Signature.
The approver's name is shown below.

Magdalena Dominiczak, 17-DEC-2020 15:07:28