

Issued by:

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Certificate of Analysis

Certificate Date	Certificate Number
08-AUG-2017	1000122627
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Material Description: AVOLVE CAPS 0.5MG 3X10
Material Number: 283162

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.	GV6P	Exp. Date	05 2021
Manf. Date	05 2017		

Importing Country:

Chile

Description	Specification	Results
Appearance	An oblong, opaque, dull-yellow, soft gelatin capsule marked with GX CE2	Complies
Identity of dutasteride (TLC)	Complies with specification	Complies
Identity of dutasteride (HPLC)	Complies with specification	Complies
Identity of Butylated Hydroxytol. (HPLC)	Complies with specification	Complies
Dutasteride content (HPLC)	0,475 - 0,525 mg/capsule	0,489
Dutasteride content (HPLC)	95,0 - 105,0 %L.C.	97,8
Uniformity of content (HPLC)	Conforms with the requirements of Ph.Eur.	Complies
Butylated Hydroxytoluene content (HPLC)	0,028 - 0,042 mg/capsule	0,034
Butylated Hydroxytoluene content (HPLC)	80 - 120 %L.C.	97
Dissolution at 45 minutes (HPLC)	Q=80%, conforms with the requirements of USP General Chapter "711"	>= 80

Qualified Person.

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

Adrianna Fraczek, 08-AUG-2017 14:48:06