



PROQUINA DOM. CONOCIDO S/N OJO DE AGUA IXTAC. VER. C.P. 94450 MEXICO	CERTIFICATE OF ANALYSIS	Page: 1 of 3 Date: 05-Aug-2016
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Material 06000574	17 ALPHA ESTRADIOL		
Batch:	5111184		
Inspection lot:	040000458307		
Manufacture date:	15-May-2016		
Date for retest:	15-May-2021		
Released quantity:	26.300 KG	Test procedure:	S4201#007581855 - 03
		Specification:	S4101#007576062 - 03

Inspection	Acceptance criterion	UoM	Result
Description	White fine powder or crystalline powder		Complies
Spectrum IR	Matches reference spectrum		Complies
Identification HPLC	Corresponds		Complies
Start of melting	222 - 226	°C	223
End of melting	222 - 226	°C	225
Specific optical rotation (Calculated on the dried basis)	51.0 - 56.0	° (+)	52.6
Loss on drying	max. 0.5	%	0.1
Sulfated ash	max. 0.1	%	0.1
Heavy metals	Not more than 0.001 %		Complies
Related substances HPLC Estradiol	max. 0.2	%	0.1
Related substances HPLC Estrone	max. 0.2	%	0.0
Related substances HPLC 4 methyl 17 alpha Estradiol	max. 0.3	%	0.1



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Inspection	Acceptance criterion	UoM	Result		
Related substances HPLC Delta 9 alpha Estradiol	max. 0.15	%	0.00		
Related substances HPLC Any unspecified impurity	max. 0.10	%	0.00		
Related substances HPLC sum (Total)	max. 1.0	%	0.2		
Residual solvent GC Isopropanol	max. 3000	ppm	0		
Residual solvent GC Ethyl acetate	max. 3000	ppm	605		
Residual solvent GC Methanol	max. 3000	ppm	0		
Residual solvent GC Tetrahydrofuran	max. 720	ppm	0		
Assay HPLC (Calculated on the dried basis)	97.0 - 102.0	%	99.3		

Batch release electronically signed:

Araceli Lopez (SHJGC)

Date/time:

06-Jun-2016 12:41:02 MX (UTC -5 hours)

Inspection lot:

040000458307

The batch corresponds to the Quality Specification and is approved.



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				Result	

Quantity to be dispatched: 0.100 kg.

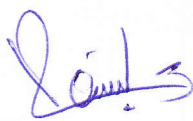
For each residual solvents, when the result is reported as "0 ppm" means below the limit of detection, as listed below:

Residual solvent GC Isopropanol, limit of detection: 36 ppm
Residual solvent GC Ethyl acetate, limit of detection: 36 ppm
Residual solvent GC Methanol, limit of detection: 54 ppm
Residual solvent GC Tetrahydrofuran, limit of detection: 17 ppm

Approved by:

Quality Manager

Ql. Roberto Bretón

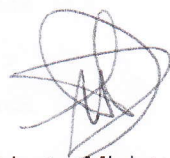

08.08.16

Compliance Manager / Responsible to Ministry of Health

Céd. Prof. 7967608

Ql. David Beristain

Tel. +52 272 74 25710



12.08.16