



PROQUINA DOM. CONOCIDO S/N OJO DE AGUA IXTAC. VER. C.P. 94450 MEXICO		CERTIFICATE OF ANALYSIS		Page: 1 of 3 Date: 08-Jun-2015	
Material 06000574		17 ALPHA ESTRADIOL			
Batch: 5106091 Inspection lot: 040000420752 Manufacture date: 20-May-2015 Date for retest: 20-May-2020 Released quantity: 18.150 KG		Test procedure: S4201#007581855 - 02 Specification: S4101#007576062 - 02			

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	°(+)	51.8
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	1234
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	%	99.7

Batch release electronically signed:

Date/time:

Inspection lot:

Araceli Lopez Martinez (SHJGC)

06-Jun-2015 21:14:12 MX (UTC -5 hours)

040000420752



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The batch corresponds to the Quality Specification and is approved.

Quantity to be dispatched: 2.001 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:
 Compliance Manager / Responsable to Ministry of Health
 QI. David Beristain
 Céd. Prof. 7967608

Handwritten signature and date:
 09.06.15
 J. M. M. 2

FAGRON IBÉRICA, S.A.U
 Corresponde al lote de Fagron:
 15607-1301
 Director Técnico