

Bayer HealthCare



PROQUINA DOM. CONOCIDO S/N OJO DE AGUA IXTAC. VER. C.P. 94450 MEXICO	CERTIFICATE OF ANALYSIS	Page: 1 of 3 Date: 06-Nov-2013
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Material	06000574	17-ALPHA ESTRADIOL
Batch:	XPB1110	
Inspection lot:	040000368013	
Manufacture date:	13-May-2013	
Date for retest:	13-May-2018	
Released quantity:	31.100 KG	Test procedure: 9374B

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	°(+)	52.8
Loss on drying	max. 0.5	%	0.0
Sulfated ash	max. 0.1	%	0.0
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	%	0.3
Residual solvent GC Isopropanol	max. 3000	ppm	0
Residual solvent GC Ethyl acetate	max. 3000	ppm	1181
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	%	100.0

Batch release electronically signed:

Araceli Lopez Martinez (SHJGC)

Date/time:

29-May-2013 09:00:06 MX (UTC -5 hours)

Inspection lot:

040000368013



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The batch corresponds to the Quality Specification and is approved.

Quantity to be dispatched: 0.500 Kg

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

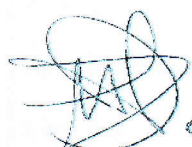
- Residual solvent GC Isopropanol, limit of detection: 36 ppm
- Residual solvent GC Ethyl acetate, limit of detection: 36 ppm
- Residual solvent GC Methanol, limit of detection: 54 ppm
- Residual solvent GC Tetrahydrofuran, limit of detection: 17 ppm

Approved by:

Compliance Manager / Responsible to Ministry of Health

QI. David Beristain

Céd. Prof. 7967608

 07.11.13