

de: 0060712

Bayer HealthCare



PROQUINA DOM. CONOCIDO S/N OJO DE AGUA IXTAC. VER. C.P. 94450 MEXICO	CERTIFICATE OF ANALYSIS	Page: 1 of 3 Date: 05-Jul-2012
Material 06000574	17-ALPHA ESTRADIOL	
Batch: XP1026X Inspection lot: 040000347718 Manufacture date: 04-Jun-2012 Date for retest: 04-Jun-2015 Released quantity: 0.500 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	°(+)	52.6
Loss on drying	max. 0.5	%	0.1
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	%	0.0



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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	%	0.1
Residual solvent GC Isopropanol	max. 3000	ppm	0
Residual solvent GC Ethyl acetate	max. 3000	ppm	1866
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:

Date/time:

Inspection lot:

Araceli López Martinez (SHJGC)

04-Jul-2012 18:46:34 MX (UTC -5 hours)

040000347718



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The batch corresponds to the Quality Specification and is approved.

Approved by:
 Compliance Manager
 QI. David Beristain

05.07.12

Responsible to Ministry of Health
 QI. Héctor Herrera
 Céd. Prof. 2510525

05.07.2012