

Bayer HealthCare



PROQUINA DOM. CONOCIDO S/N OJO DE AGUA IXTAC. VER. C.P. 94450 MEXICO		CERTIFICATE OF ANALYSIS		Page: 1 of 3 Date: 25-Sep-2015	
Material 06000574		17 ALPHA ESTRADIOL			
Batch: 5107516					
Inspection lot: 040000431405					
Manufacture date: 21-Aug-2015					
Date for retest: 21-Aug-2020					
Released quantity: 24.450 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	°(+)	52.4		
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	%	0.2		
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	%	0.05
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	946
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	%	99.5

Batch release electronically signed:

Araceli Lopez Martinez (SHJGC)

Date/time:

14-Sep-2015 17:42:29 MX (UTC -5 hours)

Inspection lot:

040000431405



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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

28.09.15