

lote: 0210914

Bayer HealthCare



Ve: PROQUINA DOM. CONOCIDO S/N OJO DE AGUA IXTAC. VER. C.P. 94450 MEXICO		CERTIFICATE OF ANALYSIS	Page: 1 of 3 Date: 04-Aug-2014
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Material	06000574	17 ALPHA ESTRADIOL
Batch:	5100461	
Inspection lot:	040000388779	
Manufacture date:	12-Apr-2013	
Date for retest:	12-Apr-2018	
Released quantity:	14.700 KG	Test procedure: S4201#007581855 - 01 Specification: S4101#007576062 - 01

Section	Acceptance criterion	UoM	Result
DOM. CONOCIDO S/N OJO DE AGUA IXTAC. VER. C.P. 94450 MEXICO			
Description	White fine powder or crystalline powder		Complies
Material			
Spectrum IR	Matches reference spectrum		Complies
Inspection lot:			
Identification HPLC	Corresponds		Complies
Date for retest:			
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
Description			
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
End of melting			
Related substances HPLC Estrone	max. 0.2	%	0.0
(Calc)			
Related substances HPLC 4 methyl 17 alpha Estradiol	max. 0.3	%	0.1
Loss			



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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	1066
Residual solvent GC Ethanol	max. 3000	ppm	0
Residual solvent GC Tetrahydrofuran	max. 720	ppm	0
Assay HPLC (Calculated on the dried basis)	97.0 - 102.0	%	99.1

Batch release electronically signed:	Araceli Lopez Martinez (SHJGC)
Date/time:	02-Apr-2014 19:15:07 MX (UTC -6 hours)
Inspection lot:	040000388779



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Section	Acceptance criterion	UoM	Result
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The batch corresponds to the Quality Specification and is approved.

Quantity to be dispatched: 1.000 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

Dr. David Beristain

Ced. Prof. 7967608