

Lote: 0060113

Bayer HealthCare



PROQUINA DOM. CONOCIDO S/N OJO DE AGUA IXTAC. VER. C.P. 94450 MEXICO		CERTIFICATE OF ANALYSIS		Page: 1 of 2 Date: 07-Jan-2013
Material 50010107		DEHYDROEPIANDROSTERONE (PRASTERONE)		
Batch: XPC0051 Inspection lot: 040000361716 Manufacture date: 27-Jan-2009 Date for retest: 27-Jan-2014 Released quantity: 10.000 KG				
Test procedure: 9930F				
Inspection	Acceptance criterion	UoM	Result	
Description	White to yellowish-white powder		Complies	
Spectrum IR	Matches reference spectrum		Complies	
Start of melting	146 - 151	°C	148	
End of melting	146 - 151	°C	149	
Specific optical rotation	10 - 14	° (+)	12	
Clarity of the solution	Clear		Complies	
Color of the solution UV/VIS Spectrophotometry (absorbance)	max. 0.030		0.003	
Loss on drying	max. 0.5	%	0.3	
Sulfated ash	max. 0.1	%	0.0	
Related substances TLC Sum	max. 1	%	0	
Related substances TLC 16 DHP acetate	max. 0.5	%	0.0	
Related substances TLC Each impurity	Not more than 0.5 %		Less than 0.5 %	
Residual solvent GC Methanol	max. 0.3	%	0.2	



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Inspection lot:	040000361716		
Manufacture date:	27-Jan-2009		
Date for retest:	27-Jan-2014		
Released quantity:	10.000 KG	Test procedure:	9930F

Inspection	Acceptance criterion	UoM	Result
Residual solvent GC Methylene chloride	max. 0.06	%	0.00
Assay HPLC	98.0 - 102.0	%	98.8

Batch release electronically signed: Araceli Lopez Martinez (SHJGC)
 Date/time: 07-Jan-2013 09:47:03 MX (UTC -6 hours)
 Inspection lot: 040000361716

The product has been analyzed and approved according to current testing standard and quality specification.

Approved by:
 Compliance Manager
 QI. David Beristain

07.01.2013

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

PA. B.F.R. Maria Peña Valero

07.01.2013