



Protocol from analyses of Testosterone propionate content in injectable oily solution.

Sample:	Testosterone propionate injectable oily solution, Magnus Pharmaceuticals, 100 mg/ml
Batch No.:	170201
Mfg. Date:	2/2017
Exp. Date:	1/2020
Standard preparation:	About 100 mg of authentic Testosterone propionate standard was weighed and transferred into 20 ml volumetric flask. 1 ml of CHCl ₃ was added to the flask and shake until dissolving of Testosterone propionate. The flask was filled with 15 ml of HPLC purity methanol (MeOH), shake for 1 minute and then put to ultrasonic bath for 20 minutes. After cooling to room temperature, flask was filled to the mark with MeOH. The standard solution was subsequently 50 times diluted with MeOH. Aliquot volume was transferred into autosampler vial and 1.0 µl was injected to HPLC-MS instrument.
Sample preparation:	1 ml of Testosterone propionate injectable oily solution was weighed (0.96587 g) into 20 ml volumetric flask. 5 ml of CHCl ₃ was added to the flask and shake until dissolving of Testosterone propionate oily solution. The flask was filled to the mark with MeOH. The sample solution was subsequently 50 times diluted with MeOH. Aliquot volume was transferred into autosampler vial and 1.0 µl was injected to HPLC-MS instrument.
Method of analyses:	HPLC-MS instrument was used for analyses of Testosterone propionate using external calibration with authentic standard of Testosterone propionate. Areas under peaks of Testosterone propionate for two MRM transitions were measured and average amount of Testosterone propionate per ml was calculated from two MRM transitions.

Calculation:

Testosterone prop.		Magnus Pharmaceuticals				
Standard	Weight (mg)	100.12	Concentration (mg/ml)	5.006		
	Volumetric flask (ml)	20	Dilution (times)	50		
MS	Purity (%)	100	Concentration (mg/ml)	0.10012		
			Inj. volume (ul)	1		
			Area MRM1 (cps*s)	7433624		
			Area MRM2 (cps*s)	2304191		
Sample	Sample weight (mg/ml)	Vol. flask (ml)	Dilution	Inj. volume (ul)	Area	Amount (mg/ml)
MRM1	965.87	20	50	1	7358257	99.105
MRM2	965.87	20	50	1	2276464	98.915
Average						99.01
STDEV						0.134
RSD (%)						0.14
Diff. (%)						0.19
% of L.C.	100	mg/ml				99.01

Conclusion:

Found amount of Testosterone propionate in "Testosterone propionate injectable oily solution, Magnus Pharmaceuticals, 100 mg/ml, Batch No.: 170201" is 99.01 mg per ml what represents 99.01% of label claim.

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Date

Signature



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