



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

Sample:	Testosterone enanthate injectable oily solution, Magnus Pharmaceuticals, 250 mg/ml
Batch No.:	170201
Mfg. Date:	2/2017
Exp. Date:	1/2020
Standard preparation:	About 100 mg of authentic Testosterone enanthate standard was weighed and transferred into 20 ml volumetric flask. 5 ml of CHCl ₃ was added to the flask and shake until dissolving of Testosterone enanthate. The flask was filled with 12 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 enanthate injectable oily solution was weighed (0.95955 g) into 50 ml volumetric flask. 15 ml of CHCl ₃ was added to the flask and shake until dissolving of Testosterone enanthate 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 enanthate using external calibration with authentic standard of Testosterone enanthate. Areas under peaks of Testosterone enanthate for two MRM transitions were measured and average amount of Testosterone enanthate per ml was calculated from two MRM transitions.

Calculation:

Testosterone enanthate		Magnus Pharmaceuticals				
Standard	Weight (mg)	99.94	Concentration (mg/ml)	4.997		
	Volumetric flask (ml)	20	Dilution (times)	50		
MS	Purity (%)	100	Concentration (mg/ml)	0.09994		
			Inj. volume (ul)	1		
			Area MRM1 (cps*s)	3790551		
			Area MRM2 (cps*s)	13925170		
Sample	Sample weight (mg/ml)	Vol. flask (ml)	Dilution	Inj. volume (ul)	Area	Amount (mg/ml)
MRM1	959.55	50	50	1	3586038	236.37
MRM2	959.55	50	50	1	13391360	240.272
Average						238.32
STDEV						2.759
RSD (%)						1.16
Diff. (%)						-1.64
% of L.C.	250 mg/ml					95.33

Conclusion:

Found amount of Testosterone enanthate in "Testosterone enanthate injectable oily solution, Magnus Pharmaceuticals, 250 mg/ml, Batch No.: 170201" is 238.32 mg per ml what represents 95.33% of label claim.

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Date

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