



Protocol from analyses of Oxandrolone content in tablets.

Sample:	Oxandrolone tablets, Magnus Pharmaceuticals, 10 mg/tablet
Batch No.:	170201
Mfg. Date:	2/2017
Exp. Date:	1/2020
Standard preparation:	About 10mg of authentic Oxandrolone standard was weighed and transferred into 20 ml volumetric flask. 2 ml of CHCl ₃ was added to the flask and shake until dissolving of Oxandrolone. 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 10 times diluted with MeOH. Aliquot volume was transferred into autosampler vial and 1.0 µl was injected to HPLC-MS instrument.
Sample preparation:	10 tablets of Oxandrolone were weighed and average weight of tablet (AWT) was calculated. Tablets were grinded in ceramic mortar and amount about AWT was weighed from powdered material of tablets and transferred into 20 ml volumetric flask. The flask was filled with 2 ml of CHCl ₃ and shake for 1 minute, then 15 ml of MeOH was added and put to ultrasonic bath for 20 minutes. After cooling to room temperature, flask was filled to the mark with MeOH and centrifuged at 9000 RPM for 5 minutes. 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 Oxandrolone using external calibration with authentic standard of Oxandrolone. Areas under peaks of Oxandrolone for two MRM transitions were measured and average amount of Oxandrolone per tablet was calculated from two MRM transitions.

Calculation:

Oxandrolone		Magnus Pharmaceuticals				
Standard	Weight (mg)	11.36	Concentration (mg/ml)	0.568		
	Volumetric flask (ml)	20	Dilution (times)	10		
MS	Purity (%)	100	Concentration (mg/ml)	0.0568		
			Inj. volume (ul)	1		
			Area MRM1 (cps*s)	4056202		
			Area MRM2 (cps*s)	1951264		
	Weight of 10 tbl (g)	1.78062	AWT (mg/tbl)	178.062		
Sample	Sample weight (mg)	Vol. flask (ml)	Dilution	Inj. volume (ul)	Area	Amount (mg/tbl)
MRM1	182.06	20	10	1	3147608	9.743
MRM2	182.06	20	10	1	1513230	9.736
Average						9.74
STDEV						0.005
RSD (%)						0.05
Diff. (%)						0.07
% of L.C.	10 mg/tbl					97.40

Conclusion:

Found amount of Oxandrolone in "Oxandrolone tablets, Magnus Pharmaceuticals, 10 mg/tablet, Batch No.: 170201" is 9.74 mg per tablet what represents 97.40 % of label claim.

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Date

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