



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

<b>Sample:</b>	Testosterone propionate injectable oily solution in ampoules, Swiss Remedies, 100 mg/ampoule
<b>Batch No.:</b>	1216-1
<b>Mfg. Date:</b>	-
<b>Exp. Date:</b>	11/19
<b>Standard preparation:</b>	About 100 mg of authentic Testosterone propionate standard was weighed and transferred into 20 ml volumetric flask. 1 ml of CHCl <sub>3</sub> 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.
<b>Sample preparation:</b>	Content of one ampoule was differentially weighed (1.01861 g) and transferred into 20 ml volumetric flask. 5 ml of CHCl <sub>3</sub> 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.
<b>Method of analyses:</b>	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 ampoule was calculated from two MRM transitions.

### Calculation:

Testosterone prop.		Swiss Remedies		
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/amp)	Vol. flask (ml)	Dilution	Inj. volume (ul)	Area	Amount (mg/ml)
MRM1	1018.61	20	50	1	7695848	103.652
MRM2	1018.61	20	50	1	2356905	102.41
Average						103.03
STDEV						0.878
RSD (%)						0.85
Diff. (%)						1.2
% of L.C.	100mg/ml					103.03

### Conclusion:

Found amount of Testosterone propionate in "Testosterone propionate injectable oily solution in ampoules, Swiss Remedies, 100 mg/ampoule, Batch No.: 1216-1" is 103.03 mg per ampoule what represents 103.03% of label claim.

Note: Volume in ampoule was a little bit higher than 1 ml.

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Date

Signature



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