



Protocol from analyses of Anastrozole content in tablets.

Sample:	Anastrazol tablets, Swiss Remedies, 1 mg/tablet
Batch No.:	170701
Mfg. Date:	0617-1
Exp. Date:	05/2022
Standard preparation:	About 10mg of authentic Anastrozole standard was weighed and transferred into 20 ml volumetric flask. 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 5.0 µl was injected to HPLC-DAD instrument.
Sample preparation:	10 tablets of Anastrazol were weighed and average weight of tablet (AWT) was calculated. Tablets were grinded in ceramic mortar and two independent weighing from powdered material of tablet were transferred into 20 ml volumetric flasks. Flasks were filled with 15 ml of MeOH, shake for 1 minute and then put to ultrasonic bath for 20 minutes. After cooling to room temperature, flasks were filled to the mark with MeOH, centrifuged at 9000 RPM for 5 minutes. Aliquot volumes were transferred into autosampler vials and 5.0 µl was injected to HPLC-DAD instrument.
Method of analyses:	HPLC-DAD instrument was used for analyses of Anastrazol using external calibration with authentic standard of Anastrozole. Areas under peaks of Anastrozole at 215 nm were measured and average amounts of Anastrozole per tablet were calculated from two samples.

Calculation:

Anastrazol		Swiss Remedies			
Standard	Weight (mg)	10.4	Concentration (mg/ml)	0.52	
	Volumetric flask (ml)	20	Dilution (times)	10	
	Purity (%)	100	Concentration (mg/ml)	0.052	
215 nm			Inj. volume (µl)	5	
			Area (mAU*s)	1019.16492	
			AWT (mg/tbl)	118.601	
	Weight of 10 tbl (g)	1.18601			
Sample	Sample weight (mg)	Vol. flask (ml)	Inj. volume (µl)	Area	Amount (mg/tbl)
m1	119.07	20	5	1027.636296	1.038
m2	120.88	20	5	1028.7282886	1.039
Average					1.039
STDEV					0.001
RSD (%)					0.08
Diff. (%)					-0.12
% of L.C.		1 mg/tbl			103.88

Conclusion:

Found amount of Anastrozole in "Anastrazol tablets, Swiss Remedies, 1 mg/tablet, Batch No.: 0617-1" is 1.039 mg per tablet what represents 103.88% of label claim.

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Date


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