



### Protocol from analyses of Clomiphene citrate content in tablets.

<b>Sample:</b>	Clomiphene tablets, Magnus Pharmaceuticals, 50 mg/tablet
<b>Batch No.:</b>	170201
<b>Mfg. Date:</b>	2/2017
<b>Exp. Date:</b>	1/2020
<b>Standard preparation:</b>	About 25 mg of authentic Clomiphene citrate standard was weighed and transferred into 50 ml volumetric flask. The flask was filled with 40 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. Aliquot volume was transferred into autosampler vial and 1.0 µl was injected to HPLC-DAD instrument.
<b>Sample preparation:</b>	10 tablets of Clomiphene 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 50 ml volumetric flasks. Flasks were filled with 40 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 1.0 µl was injected to HPLC-DAD instrument.
<b>Method of analyses:</b>	HPLC-DAD instrument was used for analyses of Clomiphene using external calibration with authentic standard of Clomiphene citrate. Areas under peaks of Clomiphene at 254 nm were measured and average amounts of Clomiphene citrate per tablet were calculated from two samples.

#### Calculation:

Clomiphene citrate					
Standard	Weight (mg)	24.69	Concentration (mg/ml)	0.4938	
	Volumetric flask (ml)	50	Inj. volume (ul)	1	
254 nm	Purity (%)	100	Area (mAU*s)	954.24188	
	Weight of 10 tbl (g)	2.97667	AWT (mg/tbl)	297.667	
Sample	Sample weight (mg)	Vol. flask (ml)	Inj. volume (ul)	Area	Amount (mg/tbl)
m1	149.23	50	1	969.96423	50.060
m2	152.15	50	1	970.94373	49.149
Average					49.605
STDEV					0.644
RSD (%)					1.30
Diff. (%)					1.84
% of L.C.	50 mg/tbl				99.21

#### Conclusion:

Found amount of Clomiphene citrate in "Clomiphene tablets, Magnus Pharmaceuticals, 50 mg/tablet, Batch No.: 170201" is 49.605 mg per tablet what represents 99.21% of label claim.

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Date

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