



# FLEMING LABORATORIES LIMITED

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## CERTIFICATE OF ANALYSIS

Product Name	FLUNARIZINE DI HCl BP/Ph.Eur.	AR.No.	FP/FLU/009/15
Batch No.	FLU/06151008	Despatch Quantity	25.0 Kg
Mfg.Date	JUN.2015	Released date	22.07.15
Retest Date	MAY-2020	DRF No.	083

S.No.	Test	Result	Specification
1.	Characters: Appearance	White hygroscopic powder.	White or almost white powder, hygroscopic.
	Solubility	Slightly soluble in water, sparingly soluble in methanol, slightly soluble in alcohol and in methylene chloride.	Slightly soluble in water, sparingly soluble in methanol, slightly soluble in alcohol and in methylene chloride.
2.	Melting point	207.6°C – 208.7°C	About 208°C, with decomposition.
3.	Identification		
	a. Infrared Absorption Spectrophotometry	Conforms	The infrared absorption spectrum of the sample is concordant with Flunarizine Dihydrochloride working standard.
	b. Test for chlorides	Conforms	The solution gives reaction of chlorides.
	Related Substances (by HPLC)		
	-Impurity-A : 1-[bis(4-fluorophenyl)methyl]piperazine	BDL	NMT 0.1 %
	-Impurity-B : 1-[(RS)-(4-fluorophenyl)phenyl methyl]-4-[(2E)-3-phenylprop-2-enyl]piperazine	0.13%	NMT 0.5 %
	-Impurity-C : 1-[(RS)-(2-fluorophenyl)(4-fluorophenyl)methyl]-4-[(2E)-3-phenylprop-2-enyl] piperazine.	BDL	NMT 0.25 %
	-Impurity-D: 1-[bis (4-fluorophenyl) methyl]-4-[(2Z)-3- phenylprop-2-enyl] piperazine.	BDL	NMT 0.1 %
	Any other Impurity	0.02%	NMT 0.1%
	Total Impurities	0.20%	NMT 1.0 %
	Loss on Drying (100°C - 105°C)	0.27% w/w	NMT 5.0 % w/w
5.	Heavy metals	Less than 20 ppm	NMT 20 ppm
6.	Sulphated Ash	0.06 % w/w	NMT 0.1 % w/w
7.	Assay % as C <sub>26</sub> H <sub>28</sub> Cl <sub>2</sub> F <sub>2</sub> N <sub>2</sub> (on dry basis)	99.16 % w/w	NLT 99.0 % and NMT 101.5 % w/w
9.	Additional Tests:		
	Residual Solvents:		
	Methanol	16 ppm	NMT 500 ppm
	Isopropyl alcohol	32 ppm	NMT 1000 ppm
	Toluene	BDL	NMT 100 ppm
	Benzene (As impurity in Toluene)	BDL	NMT 2 ppm
	b). Particle size	1.85 µ	10 % less than 10 µ
		6.37 µ	50 % less than 20 µ
		15.32 µ	90 % less than 50 µ

Remarks:- The product complies as per BP2014/ Ph.Eur 8.0 specifications.

Storage condition: In an airtight container, protected from light at about 30°C.

Prepared by : <i>(Signature)</i> Date : 27.07.15	Checked by : <i>(Signature)</i> Date : 27.07.15	Approved by : <i>(Signature)</i> Date : 27.07.15
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