

STELLENCE PHARMSCIENCE LIMITED, BANGALORE

FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : IOPAMIDOL BP/EP/In house

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Sr.No.	TESTS		SPECIFICATIONS	METHOD
1.	CHARACTERS	:	A White or almost white powder	By visual observation
2.	SOLUBILITY	:	Freely soluble in water, very slightly soluble in methanol, practically insoluble in alcohol and in methylene chloride.	as per BP
3.	IDENTIFICATION	:	Test A : IR Absorption: The sample IR spectrum should be concordant with that of Standard.	2.2.24 , as per BP
		:	Test B : Loss on drying : To comply test Loss on drying	2.2.32 as per BP
		:	Test C (Specific optical rotation) To comply test Specific optical rotation.	2.2.7 as per BP
4.	APPERANCE OF SOLUTION (2 % w/v solution in water)	:	Should be clear and colourless	2.2.1 and 2.2.2, as per BP
5.	ACIDITY OR ALKALINITY	:	Must comply	as per BP
6.	SPECIFIC OPTICAL ROTATION (400 mg per ml in water at 436 nm)	:	Between -4.6° and -5.2°	2.2.7 as per BP
7.	RELATED SUBSTANCES(BY HPLC)	:	Total impurities Not more than 0.25 %	as per BP
8.	FREE AROMATIC AMINES	:	Not more than 200 ppm	As per BP
9.	FREE IODINE	:	Not more than 10 ppm	as per BP
10.	IODIDE	:	Not more than 10 ppm	as per BP
11.	HEAVY METALS	:	Not more than 10 ppm	2.4.8 as per BP
12.	LOSS ON DRYING (Determined at 100-105°C)	:	Not more than 0.5 %	2.2.32 as per BP.
13.	SULPHATED ASH (Determined on 1.0 g)		Not more than 0.1 %	2.4.14 as per BP
14.	ORGANIC VOLATILE IMPURITIES Methanol IPA Methylene dichloride		300 ppm 500 ppm 200 ppm	By In house method

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15.*	ASSAY (CONTENT OF $C_{17}H_{22}I_3N_3O_8$ ON DRIED BASIS)	:	98.5 % to 101.0 % by potentiometric titration.	As per BP