

# STELLENCE PHARMSCIENCE LIMITED, BANGLORE

## FINISHED PRODUCT SPECIFICATIONS

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

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

