

# STELLENCE PHARMSCIENCE LIMITED, BANGALORE

## FINISHED PRODUCT SPECIFICATIONS

NAME OF THE PRODUCT : IOHEXOL BP/EP

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Sr.No.	TESTS		SPECIFICATIONS	METHOD
1.	CHARACTERS	:	White or greyish-white, hygroscopic powder.	By visual observation
2.	SOLUBILITY	:	Very soluble in water, freely soluble in methanol, practically insoluble in methylene chloride..	AS per BP
3.	IDENTIFICATION	:	Test A: IR Spectrum: The sample IR spectrum should be concordant with that of standard	2.2.24 as per BP
			Test B: Related substances: The principal peaks in the chromatogram obtained with reference solution (b) are similar in retention time and size to the peaks due to iohexol in the chromatogram obtained with reference solution (a)	2.2.27 as per BP
4.	APPEARANCE OF SOLUTION (4 % w/v solution in equal volumes of alcohol and water)	:	Should be clear and colourless	2.2.1 and 2.2.2 as per BP
5.	RELATED SUBSTANCES: By HPLC: A Sum of the impurities B,C,D, & E Sum of the impurities A & H Impurity M Impurity N Impurity O Impurity P Impurity Q Unknown Impurity Total impurity	:	Not more than 0.6 %  Not more than 0.5 %  Not more than 0.1 % Not more than 0.1 % Not more than 0.1 % Not more than 0.1 % Not mote than 0.1 % Not more than 0.1 % Not more than 1.5 %	2.2.29 As per BP
7	By TLC : B		Any individual impurity: Not more than 0.2 %.	2.2.27 As per BP

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8.	3-Chloropropane-1,2-diol ( By GC)		Not more than 25 ppm	2.2.28 As per BP
9.	FREE AROMATIC AMINE		Nor more than 500 ppm	As per BP
10.	IODIDE		Not more than 10 ppm	As per BP
11.	IONIC COMPOUND	:	Not more than 0.01 % m/m	2.2.38 As per BP.
12.	HEAVY METALS	:	Not more than 10 ppm	2.4.8 As per BP
13.	WATER( Determined 1.0 g)	:	Not more than 4.0 %.	2.5.12 As per BP
14.	ASSAY ( CONTENT OF $C_{19}H_{26}I_3N_3O_9$ ON DRIED BASIS)	:	98.0 % to 101.0 % by potentiometric titration.	As per BP