

# STELLENCE PHARMSCIENCE LIMITED, BANGALORE

## FINISHED PRODUCT SPECIFICATIONS

**NAME OF THE PRODUCT : VERAPAMIL HYDROCHLORIDE BP/EP**

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Sr.No.	TESTS	SPECIFICATIONS	METHOD
1.	<b>CHARACTERS</b>	: A white, crystalline powder,	By visual observation
2.	<b>SOLUBILITY</b>	: soluble in water, freely soluble in methanol, sparingly soluble in alcohol.	AS per BP
3.	<b>IDENTIFICATION</b>	: Test A: Ratio of absorbance: The ratio of the absorbance at the maximum at 278 nm to that at the maximum at 229 nm is 0.35 to 0.39.	2.2.25 as per BP
		Test B: IR Spectrum: The sample IR spectrum should be concordant with that of standard	2.2.24 As per BP
		Test C: TLC :The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).	2.2.27 As per BP
		Test D: Chloride reaction: It should give reaction of chlorides	2.3.1 As per BP
4.	<b>APPEARANCE OF SOLUTION</b>	: Should be clear and colourless	2.2.1 and 2.2.2 as per BP
5.	<b>OPTICAL ROTATION</b>	: Between -0.10° to + 0.10°	2.2.7 As per BP
6.	<b>pH</b>	: Between 4.5 to 6.0	2.2.3 As per BP
7.	<b>RELATED SUBSTANCES:</b> <b>By HPLC:</b> Known Impurity Unknown impurity Total impurity	:  Not more than 0.1 % Not more than 0.1 % Not more than 0.3 %	2.2.29 As per BP
8.	<b>HEAVY METALS</b>	: Not more than 10 ppm Pb	2.2.8 As per BP
9.	<b>LOSS ON DRYING</b> (Determined on 1.0 gm for 1 hours at 100 -105 °C)	: Not more than 0.5 %.	2.5.12 As per BP
10.	<b>SULPHATED ASH</b>	: Not more than 0.1 %	2.4.14 as per BP

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	(Determined on 1.0 g)			
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11.	ASSAY (CONTENT OF $C_{27}H_{39}ClN_2O_4$ .ON DRIED BASIS)	:	99.0 % to 101.0 % by potentiometric titration.	As per BP

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