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TYPICAL ANALYSIS / SPECIFICATION

PRODUCT : PROPANOLOL HCL
SHELF LIFE : FOUR YEARS SUBJECT TO CORRECT STORAGE

Test	Specification	Result
Description	White crystalline powder	Conforms
Rotation	-1.0 ⁰ - +1.0 ⁰	+0.08 ⁰
Identification	Infra-red absorbtion spectrum should be identical with contrast spectrum	Conforms
	Should be positive reaction	Conforms
Melting point	162 – 165 ⁰ C	163 – 164.5 ⁰ C
PH (25 ⁰ C)	5.0 – 6.0	5.5
Acidity or alkalinity	Conform	Conforms
Clarity and colour of solution	Conform	Conforms
Heavy metals	Conform	Conforms
Solubility	Soluble in 1% w/v water	Conforms
Loss on drying	NMT 0.5%	0.09%
Sulphated ash	NMT 0.1%	0.05%
Related substances.		
Total impurities	≤0.4%	0.27%
Single substances	≤0.1%	0.06%
Residual solvents & volatile organic impurities.		
Chloroform	≤ 60 ppm	Conforms
1,4-Dioxane	≤380 ppm	Conforms
Methylene chloride	≤600 ppm	Conforms
Tapped density	≥0.5g/ml	Conforms
Trichloroethylene	≤ 80 ppm	Conforms
Assay	99.0 – 101.0%	99.7%
Granulometry (100 mesh)	≥70%	Conforms

Conclusion: Material conforms to USP25 / BP2000