



ISOXSUPRINE HYDROCHLORIDE

CAS N. 579-56-6 CODE 921NP BATCH A210004 MAN. DATE 09/2021 RETEST DATE 09/2027

TEST FOR	SPECIFICATIONS	RESULTS
Description	white odourless crystalline powder, having a bitter taste	Complies
Identification		
· A) IR	positive	Complies
· B) UV	positive	Complies
· C) Colorimetric	positive	Complies
· D) Colorimetric	positive	Complies
Melting point	about 200°C (with decomposition) °C	202.0
pH	≥ 4.5 ≤ 6.0	4.8
Loss on drying	≤ 0.5 %	0.03
Sulphated ash (Residue on ignition)	≤ 0.2 %	0.00
Assay (UV, on dried basis)	≥ 97.0 ≤ 103.0 %	99.4
Related compounds (GC)		
· total	≤ 2.0 %	0.25
<i>Additional specifications</i>		
Related substances - Test A (HPLC)		
· imp. A - (1RS,2SR)-1-(4-hydroxyphenyl)-2-[(1RS)-1-methyl-2-phenoxy-ethylamino]propan-1-ol hydrochloride	≤ 0.2 %	Non quantifiable
Related substances - Test B (HPLC)		
· imp. B - 1-(4-hydroxyphenyl)-2-[(1-methyl-2-phenoxyethyl)amino]propan-1-one hydrochloride	≤ 0.1 %	0.02
· sum of any other impurity	≤ 0.5 %	0.18
total (Test A + Test B)	≤ 0.8 %	0.20
Residual solvents (GC)		
· acetone	≤ 1000 ppm	52

OBSERVATIONS:

- **Product complies with current USP monograph**

Copies of this CoA are not valid

APPROVED

on Sep 29, 2021

QUALITY CONTROL

Dr. R.Poli

Sep 30, 2021