

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Procainamide hydrochloride	Batch No.	20171101
Manuf. Date	2017-11-10	Expiry Date	2020-11-09
Quantity	5Kgs	Test Standard	USP 38

TEST	SPECIFICATIONS	RESULTS
Description	Almost white to yellowish crystalline powder	conform
Identification	A、B in Pass	conform
Melting point	165°C- 169°C	166°C- 169 °C
Solution transparence	50mg/mL colourless liquid	Colourless liquid
Organic volatile impurities	Meets the requirements	Complies
Limit of free p-aminobenzoic acid	≤ 0.1 %	0.04%
Residual Solvents	Ethyl alcohol ≤ 0.5%	Complies
USP Reference standards	USP Procainamide Hydrochloride RS	Complies
Loss on drying	≤ 0.3 %	0.10%
Residue on ignition	≤ 0.1 %	0.02%
Heavy Metals	≤20ppm	3ppm
Assay	98.0 - 102.0 %	99.58%

Storage: Closed keep in cool,dry and dark place ;keep from heat and strong light

Conclusion: The product complies with the requirements of USP38 standard

Quality Manager:

宋永军

Rechecker:

易洪成

Analyst:

刘琪

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