

Hallochem Group



Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Dutasteride	Batch No.	20181002
Manuf. Date	2018-10-12	Expiry Date	2021-10-11
Batch Quantity	95Kg	Test Standard	Factory standard

TEST	SPECIFICATIONS	RESULTS
Description	Off white or white crystalline powder	White crystalline powder
Identification	HPLC	conform
Loss on drying	$\leq 0.5\%$	0.08%
Melting point	246.0°C - 252.0°C	249.0°C - 250.5°C
Residue on ignition	$\leq 0.1\%$	conform
Heavy metals	$\leq 20\text{ppm}$	$< 20\text{ppm}$
Relative substance	Total Impurity $\leq 1.0\%$ Single Impurity $\leq 0.5\%$	0.06% 0.03%
Residue solvents	Acetone $\leq 5000\text{ppm}$ Dichloromethane $\leq 600\text{ppm}$ Ethyl acetate $\leq 5000\text{ppm}$ Methanol $\leq 3000\text{ppm}$ Toluence $\leq 890\text{ppm}$	Not detected Not detected 268ppm Not detected Not detected
Assay	97.0% ~ 103.0%	100.2%

Conclusion: The product complies with the requirements of Factory standard

Quality Manager:



Rechecker:



Analyst:



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