

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Cabergoline (CAS:81409-90-7)

Batch No.: DR20140102	Piece: 43g
Manufacture Date: 2014.01.02	Expiry Date: 2019.01

TESTS:

Items	Specification	Results
Appearance	White or almost white crystalline powder	Conforms
Identity	1)IR copmplies 2)X-Ray copmplies 3)HPLC copmplies	Conforms Conforms Conforms
Optical rotation	-77.0° ~ -83°	-78°
Loss on drying	≤0.5%	0.28%
Related substances	1) Cabergolin Imp A≤0.15% 2) Allylamide ≤0.10% 3) Allyl DHLA≤0.15% 4) Cabergoline oxide≤0.10% 5) Other impurities individually≤0.10% 6) Total ≤0.50%	0.05% 0.03% 0.06% 0.05% 0.04% 0.22%
Assay(HPLC)	98.0%~102.0%(recalculated on anhydrous basis)	99.5%
Residual Solvents	1.Dichloromethane ≤100ppm 2.Acetone ≤200ppm 3.Tert-butylmethylether≤200ppm 4.Xylene ≤1500ppm 5.Heptane ≤1000ppm	10ppm 25ppm 11ppm 150ppm 20ppm
Residue on ignition	≤0.10%	0.03%
Heavy metals	≤20ppm	1ppm
Particle size	90%of particles ≤80μm	Conforms
Bulk Density	0.20~0.35g/cm	0.33g/cm

Conclusion: The results conform with EP6.0/USP30.



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