



CERTIFICATE OF ANALYSIS

检 验 报 告 单

Product: Perindopril Erbumlne 培哚普利叔丁胺盐			
BATCH NO. 批号	20201101	MNF DATE 生产日期	2020.11.30
QUANTITY 数量	15Kg	TEST DATE 检验日期	2020.12.02
QUALITY STANDARD		EXP DATE 有效期	2022.12.01

Items	Specification	Test Results
Description	White or almost White crystalline powder,slightly hygroscopic	Conforms
Solubility	Freely soluble in water and in Ethanol (96%). soluble or sparingly soluble in Methylene chloride	Conforms
Solubility	Freely soluble in water and in alcohol;sparingly soluble in methylene chloride	Conforms
Identification	A)Specific Optical Rotation:-66°to -69°	-68.34°
	B)IR:Similar to the reference standard	Conforms
	C)TLC: Similar to the reference standard	Conforms
Impurity A	(By TLC) Not more than 0.25 %	Conforms
Related substances (HPLC)	Impurity B: n.m.t.0.3 %	N.D.
	Impurity E: n.m.t.0.4 %	0.05%
	Impurity F: n.m.t.0.2 %	N.D.
	Impurity H: n.m.t.0.2 %	N.D.
	Impurity I: n.m.t.0.2 %	N.D.
	Any other unknown impurity : n.m.t.0.1 %	0.021%
	Total impurities : n.m.t.1.0 %	0.083 %
Water(K.F)	Not more than 1.0 %	0.18 %
Sulphated Ash	Not more than 0.1 %	0.08 %
Heavy metals	≤20ppm	Conforms
Particle Size	d(0.9) Not more than 75µm	Conforms
Residual solvents	Methylene chloride≤0.06 %	N.D
	Ethyl acetate ≤0.5 %	0.16%
	Cyclohexane≤0.388 %	N.D
	Tetrahydrofuran≤0.072 %	N.D.
	Acetonitrile≤0.041 %	N.D.
	Pyridine≤0.02 %	N.D.
Assay by titrimetry	99.0-101.0 % on anhydrous basis	100.0%
Storage conditions	Preserve in tight container	

CONCLUSION: Pass

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