

VILDAGLIPTIN

Therapeutic Category:

Orally active anti-diabetic drugs (DPP-IV inhibitors).

Characteristics:

White crystalline powder.

Applications:

Oral hypoglycemic drug, Dipeptidyl peptidase-4 (DPP-4) inhibitor, gliptin.

Our manufacturing site uses the best available technology and operates a state of the art incinerator as a dedicated waste treatment plant.



Key Specifications: Vildagliptin

Parameters	Method	Specification
Appearance	Visual inspection	Non-hygroscopic white to slightly yellowish or slightly greyish crystalline powder
Solubility	In house specification	freely soluble in water and polar organic solvents
Identification	IR: CATM	Conforms to CRS
	HPLC Retention Time	
Water content	Karl Fisher	NMT 1.0 %
Heavy metals	USP<231>method II	NMT 10ppm
Residual on ignition	USP<281>	NMT 0.1%
Specific Optical Rotation	Polarimetric: CATM	-80° ÷ -90°
loss on drying	Vacuum oven at 100°C, until constant weight	NMT 0.5%
Melting point	DSC	145.7 ÷ 149.7°C
Assay (on anhydrous basis)	Potentiometric: CATM	98.0-102.0%
Enantiomeric purity 2R enantiomer content	Chiral HPLC:CATM	NMT 0.15%
Polymorphic identity	XRD	Confirm to Form A
Particle size	In house specification	100 µm – 200 µm
Related substances a)any single impurity b)total impurities	HPLC:CATM	a) NMT 0.1% b) NMT 0.5%
Residual solvents a)tetrahydrofuran b) acetone c)Toulene d)methyl ethyl ketone e)dichloromethane	HS-GC:CATM	a) NMT 720 PPM b) NMT 5000 PPM c) NMT 890 PPM d) NMT 5000 PPM e) NMT 600 ppm



Contact Us for more information, Tech Transfer, CMO & Quotations

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