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CERTIFICATE OF ANALYSIS

Product Name	Repaglinide	CAS No.	135062-02-1
Batch No.	P030360317A	Mfg. Date	Mar. 10, 2017
Quantity	20kg	Retest Date	Mar. 09, 2019
Packing	10kg/Drum	Report Date	Mar. 20, 2017
Specification	EP8.0		

ITEM	SPECIFICATION	RESULT
Appearance	White or almost white powder	White powder
Solubility	Practically insoluble in water, freely soluble in methanol and in methylene chloride	Complies
Identification	A. Specific optical rotation: +6.3° ~ +7.7°	+7.2°
	B. IR	Complies
Enantiomeric Purity	Impurity E ≤ 0.2%	Undetected
Related Substances		
Impurity A	≤0.1%	Undetected
Impurity B	≤0.1%	Undetected
Impurity C	≤0.1%	Undetected
Impurity D	≤0.1%	Undetected
Max Individual Unknown Impurity	≤0.10%	Undetected
Total Impurities	≤0.5%	0.04%
Loss on Drying	≤0.4%	0.16%
Sulphated Ash	≤0.1%	< 0.1%
Assay(Titrate)	99.0% ~ 101.0%	99.8%
Residual Solvents		
Methanol	≤3000ppm	Undetected
Ethanol	≤5000ppm	340ppm
Dichloromethane	≤600ppm	Undetected
Toluene	≤890ppm	Undetected
Conclusion	The product conforms to EP8.0.	
Remarks	N/A	

Analyst:

QC Manager:

QA: