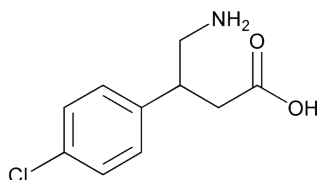


CERTIFICATE OF ANALYSIS

BACLOFEN USP



Molecular Formula: C₁₀H₁₂ClNO₂
Molecular Weight: 213.66 g/mol

Lot No. 17011901171027
CAS # 1134-47-0
Storage Condition Room Temperature

Manufacture Date 12/2016
Expiration Date 12/2021
Country of Origin India

TEST	SPECIFICATION	RESULT
Description	White to off white crystalline powder.	Complies
Solubility	Slightly soluble in Water. Very slightly soluble in Methanol. Insoluble in Chloroform.	Complies
Identification (IR)	Complies with USP specification	Complies
Identification (HPLC)	Complies with USP specification	Complies
Water Content	≤ 3.0 %	0.16 %
Residue on Ignition	≤ 0.3 %	0.10 %
Heavy Metals	≤ 10 ppm	Complies
Baclofen Related A Compound	≤ 0.05 %	ND
Impurity B	≤ 0.10 %	0.01 %
Individual Impurity	≤ 0.10 %	0.01 %
Total Impurities	≤ 1.0 %	0.02 %
Assay	99.0 - 101.0 %	99.8 %
Methanol	≤ 1500 ppm	45 ppm
Toluene	≤ 500 ppm	ND
Acetone	≤ 3000 ppm	8 ppm
Acetic Acid Content (HPLC)	≤ 3000 ppm	94 ppm
Bromide Content	≤ 500 ppm	51 ppm

Quality Signature

Compendium

Date

Conclusion



USP 40

10/27/2017

APPROVED