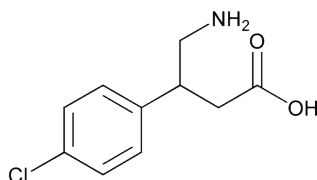


CERTIFICATE OF ANALYSIS

BACLOFEN USP



Molecular Formula: C₁₀H₁₂ClNO₂
Molecular Weight: 213.66 g/mol

Lot No. 18012601180220
CAS # 1134-47-0
Storage Condition Room Temperature

Manufacture Date 07/2017
Expiration Date 07/2022
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 %	0.20 %
Residue on Ignition	≤ 0.3 %	0.15 %
Heavy Metals	≤ 10 ppm	< 10 ppm
Baclofen Related Compound A	≤ 0.5 %	ND
Impurity B	≤ 0.10 %	ND
Individual Impurity	≤ 0.10 %	0.00 %
Total Impurities	≤ 1.0 %	0.00 %
Assay (Anhydrous)	99.0 - 101.0 %	100.2 %
Methanol	≤ 1500 ppm	17 ppm
Toluene	≤ 500 ppm	ND
Acetone	≤ 3000 ppm	7 ppm
Acetic Acid Content	≤ 3000 ppm	72 ppm
Bromide Content	≤ 500 ppm	177 ppm

Quality Signature

Compendium

Date

Conclusion



USP 40

02/20/2018

APPROVED