

**CERTIFICATE OF ANALYSIS**

Product	Baclofen USP		
Synonyms	Butanoic acid, 4-amino-3-(4-chlorophenyl)-;β-(Aminomethyl)-p-chloro hydrocinnamic acid		
CAS No.	1134-47-0	Batch No.	BACL/017/21-22
A.R. No.	MR/API/FP/22/03/021	Manufacturing date	February 2022
Batch Size	126.600 kg	Retest date	January 2027
Storage condition	Preserve in tight containers. Store at room temperature		
Date of analysis	14/03/2022		

Test	Specification	Results
Description	White to off-white, crystalline powder.	Off white powder
Solubility	Slightly soluble in water, very slightly soluble in methanol; insoluble in chloroform.	Complies
Identification (By IR)	The IR spectrum of the substance being examined should be concordant with the reference spectrum of Baclofen.	Conforms with standard
Identification (By HPLC)	The retention time of the sample solution correspond to that of the standard solution, as obtained in the assay.	Complies
Water (By KF)	Not more than 3.0%	0.14%
Residue on ignition	Not more than 0.3%	0.08%
Assay (By HPLC)	Not less than 98.0% and not more than 102.0% of Baclofen (C <sub>10</sub> H <sub>12</sub> ClNO <sub>2</sub> ) calculated on the anhydrous basis	99.67%
Organic impurities (By HPLC) 1. Baclofen related compound A 2. Any individual unspecified impurity 3. Total impurities	Not more than 1.0% Not more than 0.10% Not more than 2.0%	Not detected 0.03% 0.06%
<b>In House test</b>		
Residual solvent (By GC) Methanol	Not more than 3000 ppm	14 ppm

**Remark:** The above material Complies/does not comply with specification No. QCD/APS/020-R5

Prepared by <i>15/03/2022</i>	Checked by <i>15/03/2022</i>	Approved by <i>16/03/2022</i>
Chhote Saab Singh Gurjar Sr. Coordinator - QC	Hitesh Malvia Asst. Sr. Manager - QC	Pawan Shukla Manager-QA

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