



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	Baclofen IP	CAS No:	1134-47-0
Batch No.	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR2031

Sr No	Test	Acceptance Criteria	Results
1	Description	A White or almost white powder.	White powder.
2	Solubility	Slightly soluble in water, very slightly solubility in Ethanol (96 per cent) and practically insoluble in acetone. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.	Complies
3	Identification – By IR	The infrared absorption spectrum of test sample should be concordant with the infrared absorption spectrum of similar preparation of that of Baclofen working standard.	Complies
4	Identification – By UV	Three absorption Maxima, at 259 nm, 266 nm and 275 nm. The specific absorbance at these maxima are 9.8 to 10.8, 11.5 to 12.7 and 8.4 to 9.3 respectively.	259 nm: 10.0
5	Identification – By TLC	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	275 nm: 8.6
6	Appearance of solution	The freshly prepared solution is not more intensely colored than reference solution BY5	Complies
7	Sulphated Ash	Not more than 0.1%	0.06%
8	Water content	Not more than 1.0% w/w	0.49% w/w
9	Related Substance by HPLC Baclofen Related Impurity A	NMT 1.0%	0.51%
10	Related Substance by HPLC Total impurity	NMT 2.0%	1.16%
11	Assay by Potentiometric	Not less than 98.0% w/w and not more than 101.0 % w/w On the Previously dried basis	98.4% w/w

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayana Nehete Date: 23/05/2026 
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