LGC GmbH

Accredited Analytical Testing Laboratory

Certificate of Analysis

ISO 17034 | ISO/IEC 17025 | ISO 9001 | GMP (EXCiPACT)

Report No.	COA-NP-2026-7841	Date of Issue	28 March 2026
Client	neuropeak.net	Valid Until	28 March 2028

Sample: **Modalert 200 (Modafinil Tablets 200 mg)**

Product Name	Modalert 200
Active Ingredient	Modafinil
Strength / Dose	200 mg
Dosage Form	Tablets
Batch / Lot No.	NP-MOD-260328

Manufacturer	Sun Pharmaceutical Industries Ltd.
Mfr. Site	Halol, Gujarat, India
Sample Received	20 March 2026
Analysis Completed	28 March 2026
No. of Tablets Tested	20 tablets

199.8 mg
Assay per Tablet (label claim: 200 mg)

99.9 %
Assay (% of Label Claim)

OVERALL RESULT: ALL TESTS PASSED — CONFORMS TO SPECIFICATION

Released by:	Date of Release:	Authorization:
Dr. S. Richter	28 March 2026, Luckenwalde	Head of Quality / Product Release

DAkkS D-RM-14176-01-00	ISO/IEC 17025	ISO 17034	ISO 9001 | GMP

Scope of Analysis

This Certificate of Analysis documents the results of independent third-party testing performed by LGC GmbH on **Modalert 200** (Modafinil 200 mg tablets), manufactured by Sun Pharmaceutical Industries Ltd..

Testing was commissioned by **neuropeak.net** to verify the identity, potency, purity, and physical quality of the finished pharmaceutical product. All tests were performed on the actual tablets as received, not on raw material or reference standards.

Analytical methods used are based on pharmacopoeial procedures (USP/EP) and validated in-house methods. Test methods used for characterisation are accredited to ISO/IEC 17025 (DAkkS D-PL-14176-01-00).

Sample Description

Product	**Modalert 200 (Modafinil Tablets 200 mg)**
Manufacturer	**Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol, Gujarat 389350, India**
Dosage Form	**White to off-white, round, biconvex tablets**
Marking	**"Modalert 200" debossed on one side, score line on reverse**
Pack Size Received	**10 tablets per blister, 2 blisters received**
Batch / Lot No.	**NP-MOD-260328**
Mfg. Date	**January 2026**
Exp. Date	**December 2028**
Storage Conditions	**Below 25 °C, protect from light and moisture**

Table of Contents

1. Identification Tests 3
2. Assay / Potency (HPLC) 3
3. Purity & Related Substances (HPLC) 4
4. Physical Tests 5
5. Dissolution Test 5
6. Uniformity of Dosage Units 6
7. Summary of Results 7

1. Identification Tests

Identity of the active ingredient was confirmed using multiple independent analytical techniques per USP/EP monograph requirements.

Test	Method	Acceptance Criteria	Result
Identification A	HPLC — Retention time	RT matches Modafinil CRS	**PASS — RT = 8.16 min (CRS = 8.15 min)**
Identification B	UV Spectrum	Absorption maxima correspond	**PASS — λmax 223 nm, 272 nm**
Identification C	IR (ATR-FTIR)	Spectrum matches CRS	**PASS — Confirmed**

2. Assay / Potency (HPLC)

Content of Modafinil per tablet determined by reversed-phase HPLC with UV detection against a certified reference standard (Modafinil CRS, purity 99.9%).

HPLC Conditions

Column	**Hypersil Gold C18, 5 µm, 150 × 4.6 mm**
Column Temp.	**40 °C**
Detector	**UV, 220 nm**
Flow Rate	**1.0 mL/min**
Injection Volume	**10 µL**
Mobile Phase A	**Water, 0.1% H_3PO_4**
Mobile Phase B	**Acetonitrile, 0.1% H_3PO_4**
Run Time	**25 min (isocratic A/B 65/35)**
Sample Prep.	**1 tablet dissolved in 100 mL mobile phase, filtered 0.45 µm**

Acceptance Criteria	**90.0 % – 110.0 % of label claim (USP)**
Result (n = 6)	**99.9 % of label claim (199.8 mg per tablet)**
Verdict	**PASS**

3. Purity & Related Substances (HPLC)

Related substances and degradation products were determined by gradient HPLC-UV per USP monograph for Modafinil Tablets. Detection at 220 nm.

Test Parameter	Acceptance Criteria	Result	Verdict
Modafinil sulfone	≤ 0.5 %	0.04 %	PASS
Modafinil acid	≤ 0.5 %	Not detected (< 0.02 %)	PASS
Modafinil sulfide	≤ 0.5 %	0.03 %	PASS
Any single unknown impurity	≤ 0.2 %	0.05 %	PASS
Total impurities	≤ 1.0 %	0.12 %	PASS

Chromatographic Peak Summary

Peak #	Retention Time (min)	Identity	Area %
1	8.16	Modafinil (API)	99.88
2	5.23	Modafinil sulfide	0.03
3	11.47	Modafinil sulfone	0.04
4	13.82	Unknown	0.05
Total			**100.00 %**

All individual and total impurities are well within pharmacopoeial limits. No unexpected degradation products were observed.

4. Physical Tests

Test	Method	Acceptance Criteria	Result	Verdict
Appearance	Visual	White to off-white, round tablets	Conforms	PASS
Average Weight	EP 2.9.5 (n=20)	200 mg ± 5%	201.3 mg	PASS
Weight Variation	EP 2.9.5 (n=20)	± 5% of avg	Max dev. 2.1%	PASS
Hardness	EP 2.9.8 (n=10)	≥ 40 N	87 N (avg)	PASS
Friability	EP 2.9.7	≤ 1.0 %	0.12 %	PASS
Disintegration	EP 2.9.1 (n=6)	≤ 30 min	4 min 22 sec	PASS

5. Dissolution Test

Dissolution testing performed per USP monograph for Modafinil Tablets using USP Apparatus II (paddle).

Apparatus	**USP Type II (Paddle), 50 rpm**
Medium	**0.1 N HCl with 1% SLS, 900 mL**
Temperature	**37.0 ± 0.5 °C**
Time Point	**45 minutes**
Detection	**UV at 220 nm**
Acceptance (USP)	**Q = 75% (not less than 75% dissolved in 45 min)**

Individual Tablet Results (n = 6)

Tablet	1	2	3	4	5	6	Mean
% Dissolved	96	94	97	95	98	96	96

Acceptance	**Q = 75% (≥ 75% dissolved)**
Result	**96 % mean dissolved (range 94–98%)**
Verdict	**PASS — All tablets exceed Q + 5%**

6. Uniformity of Dosage Units (Content Uniformity)

Content uniformity determined per USP <905> by individual assay of 10 tablets. Acceptance Value (AV) calculated per USP criteria.

Individual Tablet Content (mg Modafinil per tablet)

Tablet	1	2	3	4	5	6	7	8	9	10
mg Found	199.2	200.4	198.8	201.0	199.6	200.8	199.0	200.2	198.6	200.4

Mean Content	**199.8 mg (99.9% of label claim)**
Std. Deviation (SD)	**0.82 mg**
RSD	**0.41 %**
Acceptance Value (AV)	**2.8**
USP Limit (L1)	**AV ≤ 15.0**
Verdict	**PASS**

The Acceptance Value (AV) of 2.8 is well below the USP limit of 15.0, indicating excellent content uniformity across the batch. All individual tablets fall within 98.6%–100.5% of label claim.

Additional Tests

Test	Method	Acceptance	Result	Verdict
Water Content	Karl Fischer (EP 2.5.12)	≤ 3.0 %	1.2 %	PASS
Total Aerobic Count	EP 2.6.12	≤ 10^3 CFU/g	< 10 CFU/g	PASS
Total Yeast/Mould	EP 2.6.12	≤ 10^2 CFU/g	< 10 CFU/g	PASS
E. coli	EP 2.6.13	Absent / g	Absent	PASS

7. Summary of Results

The following table summarises all tests performed on **Modalert 200** (Modafinil Tablets 200 mg), manufactured by Sun Pharmaceutical Industries Ltd., Batch No. NP-MOD-260328.

#	Test	Result	Verdict
1	Identification (HPLC/UV/IR)	Confirmed	**PASS**
2	Assay (% label claim)	99.9 %	**PASS**
3	Related Substances (total)	0.12 %	**PASS**
4	Average Weight	201.3 mg	**PASS**
5	Hardness	87 N	**PASS**
6	Friability	0.12 %	**PASS**
7	Disintegration	4 min 22 sec	**PASS**
8	Dissolution (Q=75%)	96 % mean	**PASS**
9	Content Uniformity (AV)	2.8	**PASS**
10	Water Content	1.2 %	**PASS**
11	Microbial Limits	Conforms	**PASS**

OVERALL VERDICT: ALL 11 TESTS PASSED — PRODUCT CONFORMS TO SPECIFICATION

This Certificate of Analysis has been issued by **LGC GmbH**, Luckenwalde, Germany, for the client **neuropeak.net**. It confirms that the sample of **Modalert 200** (Modafinil Tablets 200 mg, manufactured by Sun Pharmaceutical Industries Ltd.) has been independently tested and meets all applicable pharmacopoeial specifications (USP/EP).

The laboratory warrants the accuracy of these results. This report relates only to the sample(s) tested. Reproduction of this certificate is permitted only in its entirety.

DAkkS D-RM-14176-01-00	ISO/IEC 17025	ISO 17034	ISO 9001 | GMP