CERTIFICATE OF ANALYSIS

MODAFINE 200

PRODUCT PARTICULARS	DETAILS	PRODUCT PARTICULARS	DETAILS
Product name	Modafine 200	Generic name	Modafinil Tablets USP 200 mg
Product code	301MODA08	Specification	USP
SFG batch no.	HT-26092	Batch size	200,000.0 tabs
FG batch no.	HT-26092	A. R. no.	FP260391
Manufacturing date	05/2026	Expiry date	04/2029
Specification no.	H/SPC/FP/267	STP no.	H/STP/FP/267
Release date	15/07/2026	Market	NA

TEST RESULTS

SR. NO.	TEST	RESULT	SPECIFICATION
1	Description	White colour, uncoated tablet, round shaped, breakline on one side and plain on other side.	White to off-white colour, uncoated tablet, round shaped, breakline on one side and plain on other side.
2	Average weight	369.90 mg	360.00 mg ± 5% (342.00 mg to 378.00 mg)
3	Uniformity of weight	(-) Deviation: -3.3% (+) Deviation: +1.8%	± 5% of avg. weight
4	Identification by IR	Complies	Meets the requirements over the range from 1700-400 cm^{-1}
5	Disintegration	01 min 44 sec	NMT 15 min
6	Thickness	Min: 3.89 mm Max: 4.02 mm Avg: 3.97 mm	3.90 mm ± 0.30 mm (3.60 mm to 4.20 mm)
7	Hardness	Min: 59 N Max: 105 N Avg: 76 N	NLT 30 N
8	Friability	0.2%	NMT 1.0%
9	Dissolution	Min: 87% Max: 94% Avg: 91%	Not less than 75% (Q) of the labeled amount of Modafinil is dissolved

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TEST RESULTS (CONTINUED)

SR. NO.	TEST	RESULT	SPECIFICATION
10	Organic impurities (by HPLC)	Modafinil acidb: Not detected Modafinil Sulfonec: Not detected Any individual unspecified impurity: Not detected Total impurities: Not detected	Modafinil acidb: NMT 0.5% Modafinil Sulfonec: NMT 0.5% Any individual unspecified impurity: NMT 0.2% Total impurities: NMT 1.5%
11	Assay	101.9% (203.85 mg)	Each uncoated tablet contains: Modafinil USP 200 mg (90% to 110%)

REMARKS

The above sample complies with the specification.