BRAWN LABORATORIES LTD.

BRAWN LABORATORIES LIMITED

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Mfg Lic No: 671-OSP(H) + 379B-(H)

The Drugs & Cosmetics Act 1940 and the Rules thereunder

CERTIFICATE OF ANALYSIS

REPORT NO : **BF/TAB/24-2501/024**
SAMPLE : **COCILONE**
GENERIC NAME : COLCHICINE TABLETS BP 1MG
BATCH NO : BNT0125003
BATCH SIZE : 2500000 TBS
SAMPLE QTY : 60.00 TBS
REF. PROTOCOL : BP-2016.
COMPLETION DATE : 22/01/2025

RECEIVED ON : 09/01/2025
STAGE : FINISHED
MFG. DATE : 06/01/2025
EXP. DATE : 05/01/2028

TEST	RESULTS	SPECIFICATION
Description	White coloured, round, uncoated tablets with scored-line on one side.	White coloured, round, uncoated tablets with scored-line on one side.
Identification		
A. By UV Absorption	246nm=1.022 and 352nm=0.588.	The light absorption, in the range 220 to 400nm exhibits two maxima, at 246nm and 352nm.
B. By HPLC	In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) corresponds to that of the principal peak in the chromatogram obtained with solution (2).	In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) corresponds to that of the principal peak in the chromatogram obtained with solution (2).
C. By Methyl Hydroxybenzoate and Propyl Hydroxybenzoate	Retention time of Methyl Hydroxybenzoate and Propyl Hydroxybenzoate peaks in test solution chromatogram is correspondent to that in reference solution chromatogram obtained in the conditions specified for Methyl Hydroxybenzoate and Propyl Hydroxybenzoate Assay test.	Retention time of Methyl Hydroxybenzoate and Propyl Hydroxybenzoate peaks in test solution chromatogram must be correspondent to those in reference solution chromatogram obtained in the conditions specified for Methyl Hydroxybenzoate and Propyl Hydroxybenzoate Assay test.
Average Weight	154.0mg	154mg ± 5%
Uniformity of Weight	-2.14 to +2.14%	± 7.5% of Average Weight
Uniformity of Content	99.10 - 103.83%	85.0 - 115.0%
Dissolution	101.42 - 106.70%	NLT 75%(Q) is dissolve in 45 minutes.
Related Substances (By HPLC)		
Impurity A	Not detected	NMT 3.5%
Any other secondary peak	0.003%	NMT 1.0%
Sum of the areas of all the Secondary Peaks	0.003%	NMT 5.0%
Assay		

Each uncoated tablet contains:

Ingredients	Obtained	Claim	Limit
Colchicine BP	1.013 mg	1.000 mg	0.95-1.05 mg
.	101.3%		95.0 - 105.0% of the label claim
Methyl Hydroxybenzoate	0.2508 mg	0.250 mg	0.2-0.3 mg
..	100.31%		80.0 - 120.0% of the label claim
Propyl Hydroxybenzoate	0.0577 mg	0.060 mg	0.048-0.072 mg
.	96.14%		80.0 - 120.0% of the label claim

REPORT : In the opinion of the undersigned the sample referred above is of standard quality as per BP-2016.

MANUFACTURER : BRAWN LABORATORIES LIMITED

	ANALYSED BY	CHECKED BY	APPROVED BY
SIGNATURE			
DATE	22/01/2025	22/01/2025	22/01/2025
NAME	RAHUL KUMAR	BIPIN KUMAR JHA	HAWALDAR PANDEY
DESIGNATION	EXECUTIVE	Sr. EXECUTIVE	Sr. MANAGER-QC