WRS I 1-5

AUROCHEM
AUROCHEM Laboratories (India) Pvt. Ltd.

333, Gundecha Industrial Complex, 3rd Floor,
Akurli Road, Kandivali (East), Mumbai - 400 101.
Tel.: + 91 22 2885 8503 / 04 / 05 / 022-42508181
Fax : + 91 222887 3236
E-Mail: info@aurochemgroup.com
Website : www.aurochemlaboratories.com
CIN: U24230MH1997PTC112098

"GOVERNMENT RECOGNIZED EXPORT HOUSE"

WORKING STANDARD REPORT

Preparation Date	04/10/2017	Valid upto	04/10/2018
Manufacturer	Iol Chemicals & Pharmaceuticals Ltd	Page no	1/2
Item Name	**IBUPROFEN BP**	Mfg. Date	Aug 2017
Batch No	4000/1201/17/A-0087P	Exp. Date	Jul 2022
Storage condition	Store below 25°C	Quantity	500 mg

	TEST	OBSERVATIONS	STANDARD
01.	Description	A White Crystalline powder.	White or almost white, crystalline powder or colourless crystals.
02.	Solubility	Practically insoluble in water, freely soluble in acetone, in methanol and in methylene chloride. It dissolves in diiute solutions of alkali hydroxides and carbonates.	Practically insoluble in water, freely soluble in acetone, in methanol and in methylene chloride. It dissolves in dilute solutions of alkali hydroxides and carbonates.
03.	Identification		
	A. Melting Point	77.6°C	75°C to 78°C
	B. Ultraviolet and visible absorption spectrophotometry	A_{264} / A_{258}:1.234 A_{272} / A_{258}:1.040	A_{264} / A_{258}=1.20 to 1.30 A_{272} / A_{258}=1.00 to 1.10
	C. Infrared absorption spectrophotometry	The IR spectrum of the sample preparation is concordant to the Reference spectrum of Ibuprofen.	The IR spectrum of the sample preparation is concordant to the Reference spectrum of Ibuprofen.
	D. Thin-layer chromatography	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.
04.	Appearance of solution	Solution is clear and colourless.	Solution should be clear and colourless.
05.	Optical Rotation	+ 0.03°	+0.05° to +0.05°

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
18 DEC 2017
TEL: 2726943 / 3544525/30
FAX: 2718073
P. O. Box 29726 - 00202, NAIROBI

T 1-5

WRS

I1-5

AUROCHEM
AUROCHEM Laboratories (India) Pvt. Ltd.

333, Gundecha Industrial Complex, 3rd Floor,
Akurli Road, Kandivali (East), Mumbai - 400 101.
Tel.: + 91 22 2885 8503 / 04 / 05 / 022-42508181
Fax : + 91 222887 3236
E-Mail: info@aurochemgroup.com
Website : www.aurochemlaboratories.com
CIN: U24230MH1997PTC112098

"GOVERNMENT RECOGNIZED EXPORT HOUSE"

WORKING STANDARD REPORT

Preparation Date	04/10/2017	Valid upto	04/10/2018
Manufacturer	Iol Chemicals & Pharmaceuticals Ltd	Page no	2/2
Item Name	**IBUPROFEN BP**	Mfg. Date	Aug 2017
Batch No	4000/1201/17/A-0087P	Exp. Date	Jul 2022
Storage condition	Store below 25°C	Quantity	500 mg

	TEST	OBSERVATIONS	STANDARD
06.	Related substances		
	i) Impurities A,J,N	Less than 0.15 %	For each impurity, Not more than 0.15%
	ii)Unspecified Impurities	Less than 0.05 %	For each impurity ,Not more than 0.05 %
	iii)Total Impurities	Less than 0.2 %	Not more than 0.2%
	iv)Impurity F	Less than 0.1 %.	Maximum 0.1 %.
	v) Disregard limit	Less than 0.03 %.	Not more than 0.03 %.
07.	Heavy Metals	Less than 10 ppm	Maximum 10 ppm
08.	Loss on Drying	0.35 %	Maximum 0.5 %.
09.	Sulfated ash	0.04 %	Maximum 0.1 %.
10.	Assay $C_{13}H_{18}O_2$	99.97% On as is basis 100.32 % on dried basis.	98.5 % to 101.0 % on dried basis

AUROCHEM LABORATORIES (I) PVT. LTD. QUALITY CONTROL UNIT

In the opinion of undersigned the sample referred to above IS OF STANDARD QUALITY as defined in the Act and Rules made there under in above respect, as per BP & can be used as Working Standard.

ANALYSED BY	CHECKED BY
04/10/2017	04/10/2017

AUROCHEM LABORATORIES (I) PVT. LTD.

04/10/2017

Trupti Churi

Quality Control Manager

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
18 DEC 2017
TEL: 2726963 / 3544525/30
FAX: 2716078
P. O. Box 29726 - 00202, NAIROBI

I1-5