WRS
D48-1

UTTARANCHAL BIOTECH LTD

DOLMEN 30mg
(Duloxetine Hydrochloride Tablets)

Working Standard of Duloxetine Hydrochloride of API Manufacturer:

NATIONAL QUALITY CONTROL LABORATORY
DOCUMENTATION
20 -05- 2016
Tel: 2726963/3544525/30,
Fax: 2718073
P.O Box 29719-00202, NAIROBI

SHODHANA LABORATORIES LIMITED

CERTIFICATE OF ANALYSIS

Name: Duloxetine hydrochloride

Batch No.: DH-051/15

Batch Qty: 11.0Kgs

Manufactured In: April 2015

Retest In: March 2018 AR.No: FP- 0639/15

S.No	Test	Specification	Result
01	Description	An off- white to white colored powder	An off- white colored powder
02	Solubility	Soluble in methanol	Soluble in methanol
03	Identification By IR By HPLC	The sample spectrum should be in concordant with that of working standard. The retention time of the principal peak in sample chromatogram should match with that of the principal peak in the chromatogram obtained with working standard in" Related substances by HPLC"test	Complies Complies
04	Water by KF	Not more than 0.5% w/w	0.22% w/w
05	Loss on drying	Not more than 0.5% w/w	0.13% w/w
06	Sulphated ash	Not more than 0.1%w/w	0.07%w/w
07	Heavy metals	Not more than 10ppm	Below 10 ppm
08	Assay (On dried basis)	Between 98.0% - 102.0% w/w	100.0% w/w
09	Related substances by HPLC i) Single maximum impurity ii) Total impurities	 Not more than 0.5% Not more than 1.0%	 0.11% 0.17%
10	Specific optical rotation (C=1.0%w/v solution in methanol)	(+) 115.0° to (+) 123.0°	(+) 121.113°

This material complies/~~does not comply~~ with the above specifications

Compiled by
Date: 21-07-2015

Approved by
Date: 21-07-2015

20

Certificate of Analysis of Duloxetine Hydrochloride from API Manufacturer:

SHODHANA LABORATORIES LIMITED

CERTIFICATE OF ANALYSIS

Name: Duloxetine hydrochloride

Batch No.: DH-049/15

Batch Qty: 10.0Kgs

Manufactured In: June 2015

Retest In: May 2018 AR.No: FP- 0601/15

S.No	Test	Specification	Result
01	Description	An off- white to white colored powder	An off- white colored powder
02	Solubility	Soluble in methanol	Soluble in methanol
03	Identification By IR By HPLC	The sample spectrum should be in concordant with that of working standard. The retention time of the principal peak in sample chromatogram should match with that of the principal peak in the chromatogram obtained with working standard in" Related substances by HPLC"test	Complies Complies
04	Water by KF	Not more than 0.5% w/w	0.25% w/w
05	Loss on drying	Not more than 0.5% w/w	0.13% w/w
06	Sulphated ash	Not more than 0.1%w/w	0.04%w/w
07	Heavy metals	Not more than 10ppm	Below 10 ppm
08	Assay (On dried basis)	Between 98.0% - 102.0% w/w	100.3 % w/w
09	Related substances by HPLC i) Single maximum impurity ii) Total impurities	 Not more than 0.5% Not more than 1.0%	 0.01% 0.06%
10	Specific optical rotation (C=1.0%w/v solution in methanol)	(+) 115.0° to (+) 123.0°	(+) 121.189°

This material complies/~~does not comply~~ with the above specifications

Compiled by
Date: 21-07-2015

Approved by
Date: 21-07-2015

| Factory : Plot No. 24, 25 & 26, Phase -1, IDA, Jeedimetla, Hyderabad - 500 055, Telangana, India. E-mail : info@shodhana.com, www.shodhana.com |

SHODHANA LABORATORIES LIMITED

CERTIFICATE OF ANALYSIS

Name: Duloxetine hydrochloride

Batch No.: DH-050/15

Batch Qty: 10.0Kgs

Manufactured In: June 2015

Retest In: May 2018 AR.No: FP- 0619/15

S.No	Test	Specification	Result
01	Description	An off- white to white colored powder	An off- white colored powder
02	Solubility	Soluble in methanol	Soluble in methanol
03	Identification By IR By HPLC	The sample spectrum should be in concordant with that of working standard. The retention time of the principal peak in sample chromatogram should match with that of the principal peak in the chromatogram obtained with working standard in" Related substances by HPLC"test	Complies Complies
04	Water by KF	Not more than 0.5% w/w	0.26% w/w
05	Loss on drying	Not more than 0.5% w/w	0.34% w/w
06	Sulphated ash	Not more than 0.1%w/w	0.03%w/w
07	Heavy metals	Not more than 10ppm	Below 10 ppm
08	Assay (On dried basis)	Between 98.0% - 102.0% w/w	100.1% w/w
09	Related substances by HPLC i) Single maximum impurity ii) Total impurities	 Not more than 0.5% Not more than 1.0%	 0.04% 0.04%
10	Specific optical rotation (C=1.0%w/v solution in methanol)	(+) 115.0° to (+) 123.0°	(+) 122.246°

This material complies/~~does not comply~~ with the above specifications

Compiled by
Date: 21-07-2015

Approved by
Date: 21-07-2015

| Factory : Plot No. 24, 25 & 26, Phase -1, IDA, Jeedimetla, Hyderabad - 500 055, Telangana, India. E-mail : info@shodhana.com, www.shodhana.com |

SHODHANA LABORATORIES LIMITED

CERTIFICATE OF ANALYSIS

Name: Duloxetine hydrochloride

Batch No.: DH-051/15

Batch Qty: 11.0Kgs

Manufactured In: April 2015

Retest In: March 2018 AR.No: FP- 0639/15

S.No	Test	Specification	Result
01	Description	An off- white to white colored powder	An off- white colored powder
02	Solubility	Soluble in methanol	Soluble in methanol
03	Identification By IR By HPLC	The sample spectrum should be in concordant with that of working standard. The retention time of the principal peak in sample chromatogram should match with that of the principal peak in the chromatogram obtained with working standard in" Related substances by HPLC"test	Complies Complies
04	Water by KF	Not more than 0.5% w/w	0.22% w/w
05	Loss on drying	Not more than 0.5% w/w	0.13% w/w
06	Sulphated ash	Not more than 0.1%w/w	0.07%w/w
07	Heavy metals	Not more than 10ppm	Below 10 ppm
08	Assay (On dried basis)	Between 98.0% - 102.0% w/w	100.0% w/w
09	Related substances by HPLC i) Single maximum impurity ii) Total impurities	 Not more than 0.5% Not more than 1.0%	 0.11% 0.17%
10	Specific optical rotation (C=1.0%w/v solution in methanol)	(+) 115.0° to (+) 123.0°	(+) 121.113°

This material complies/~~does not comply~~ with the above specifications

Compiled by
Date: 21-07-2015

Approved by
Date: 21-07-2015

20