

**Laboratory**                      **Torrent Pharmaceuticals Limited, Research Centre, Analytical & Bio Analytical Laboratories, Ahmedabad Airport-Gandhinagar Highway, Village Bhat, Tal. & Dist. Gandhinagar, Gujarat**

**Accreditation Standard**    **ISO/IEC 17025: 2017**

**Certificate Number**        **TC-8081 (in lieu of T-0491)**                      **Page 1 of 16**

**Validity**                            **08.12.2018 to 07.12.2020**                      **Last Amended on --**

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
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**CHEMICAL TESTING**

I.	<b>DRUGS &amp; PHARMACEUTICALS</b>			
<b>A.</b>	<b>Pharmaceutical Raw Material - General Tests</b>	Bulk density	BP 2018 Appendix XVII-S (V534) IP 2018- 2.4.35 (Page no. 272) USP41-NF36 <616> (Page no. 6360) EP 9.0-2.9.34 (Page no. 359)	0.2 g/cc to 2.0 g/cc
		Heavy metals	BP 2018 Appendix VII (V273) IP 2018- 2.3.13 (Page no. 139) USP39-NF34 <228> (Page no. 266) EP 9.0- 2.4.8 (Page no. 133)	Qualitative
		pH	BP 2016 Appendix V-L (V252) IP 2018 – 2.4.24 (Page no. 215) USP41-NF36 <791> (Page no. 6543) EP 9.0- 2.2.3 (Page no. 24)	0.5 to 14.0
		Residue on ignition	USP41-NF36 <268> (Page no. 6168)	0.01% to 0.1%
		Sulphated ash	IP 2018- 2.3.18 (Page no. 140) EP 9.0 -2.4.14	0.01% to 0.1%

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		Loss on drying	(Page no. 136) BP 2018 Appendix IX-E (V309) IP 2018 -2.4.19 (Page no. 156) USP41-NF36 <731> (Page no. 6485) EP 9.0- 2.2.32 (Page no. 53)	0.01% to 1.0 %
		Molecular mass using LC-MS	GTP/IH/003/02 Effective Date: 19.03.2016	50 to 2000 m/z
		Recording of IR spectra	GTP/IH/006/00 Effective Date: 21.09.2010	4000 cm <sup>-1</sup> to 400 cm <sup>-1</sup>
		Particle size distribution	GTP/IH/007/00 Effective Date: 21.09.2010	0.02 to 2000µ
		Polymorphic identification by X-ray Powder Diffractometer	GTP/IH/011/00 Effective Date: 21.09.2010	2° to 40° 2theta
		Specific Surface Area	GTP/IH/008/00 Effective Date: 21.09.2010	0.2 to 15 m <sup>2</sup> /g
		General Test- Proton NMR	GTP/IH/010/00 Effective Date: 21.09.2010	( -1 to 16)
		General Test- <sup>13</sup> C NMR		( -1 to 270)
		Total ash	BP 2018 Appendix XI J (V335) IP 2018 -2.3.19 (Page no.1408) EP 9.0 2.4.16 (Page no. 137)	0.01% to 0.1%
		Specific rotation	GTP/IH/004/00 Effective Date: 21.09.2010	0° to 360°
		Water / Moisture Content	BP 2018 Appendix IX-C (V307)	0.01% to 100%

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			IP 2018-2.3.43 (Page. 156) EP 9.0- 2.5.12 (Page no. 165) USP41-NF36 <921> (Page no. 6687)	
		Identification and melting point by differential scanning calorimeter(DSC)	GTP/IH/009/01 Effective Date: 08.07.2014	(-)60°C to 450°C
		Thermogravimetric analysis	BP 2018 Appendix V-M (V253) IP 2018-2.4.31 (Page no. 259) EP 9.0- 2.2.34 (Page no. 57) USP41-NF346 <891> (Page no. 6669)	Room Temperature to 1000°C
<b>B.</b>	<b>Pharmaceutical Finished Product - General Tests</b>	Uniformity of dispersion	IP 2014 (Page no. 1120)	Qualitative test
Disintegration test		BP 2018 Appendix XII -A (V347) IP 2018 -2.5.1 (Page no. 299) USP41-NF36 <701> (Page no. 6455) EP 9.0-2.9.1 (Page no. 299)	05 seconds to 99 minutes 59 seconds	
Water / Moisture Content		BP 2018 Appendix XI -C (V-307) IP 2018-2.3.43 (Page.156) EP 9.0 2.5.12 (Page no.165) USP41-NF36 <921> (Page no. 6687)	0.01% to 100%	

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<b>C.</b>	<b>PHARMACEUTICAL RAW MATERIAL - SPECIFIC TESTS</b>			
<b>1.</b>	<b>Anagrelide Hydrochloride</b>	<b>Residual Solvents</b> Toluene	RMT/2841/06 Effective Date: 27.02.2018 RMT/2842/05 Effective Date: 11.04.2017	1 µg/mL to 15000 µg/mL
		Methanol	RMT/2841/06 Effective Date: 27.02.2018 RMT/2842/05 Effective Date: 11.04.2017	1 µg/mL to 15000 µg/mL
		Tert Butyl methyl ether	RMT/2841/06 Effective Date: 27.02.2018 RMT/2842/05 Effective Date: 11.04.2017	1 µg/mL to 15000 µg/mL
		Benzene	RMT/2841/06 Effective Date: 27.02.2018 RMT/2842/05 Effective Date: 11.04.2017	1 µg/mL to 15000 µg/mL
		Ethanol	RMT/2841/06 Effective Date: 27.02.2018 RMT/2842/05 Effective Date: 11.04.2017	1 µg/mL to 15000 µg/mL
<b>2.</b>	<b>Olmesartan Medoxomil</b>	<b>Residual Solvents</b> Acetone	RMT/1653/10 Effective Date: 01.02.2018 RMT/1187/04 Effective Date: 15.03.2017 RMT/1564/06 Effective Date: 18.01.2018	1 µg/mL to 15000 µg/mL
		Ethyl acetate	RMT/1653/10 Effective Date: 01.02.2018 RMT/1187/04 Effective Date: 15.03.2017	1 µg/mL to 15000 µg/mL

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			RMT/1564/06 Effective Date: 18.01.2018	
		Isopropyl alcohol	RMT/1653/10 Effective Date: 01.02.2018 RMT/1187/04 Effective Date: 15.03.2017 RMT/1564/06 Effective Date: 18.01.2018	1 µg/mL to 15000 µg/mL
		Methylene chloride	RMT/1653/10 Effective Date: 01.02.2018 RMT/1187/04 Effective Date: 15.03.2017 RMT/1564/06 Effective Date: 18.01.2018	1 µg/mL to 15000 µg/mL
		Methanol	RMT/1653/10 Effective Date: 01.02.2018 RMT/1187/04 Effective Date: 15.03.2017 RMT/1564/06 Effective Date: 18.01.2018	1 µg/mL to 15000 µg/mL
		Dimethyl acetamide	RMT/1653/10 Effective Date: 01.02.2018 RMT/1187/04 Effective Date: 15.03.2017 RMT/1564/06 Effective Date: 18.01.2018	1 µg/mL to 15000 µg/mL
		Acetic acid	RMT/1653/10 Effective Date: 01.02.2018 RMT/1187/04 Effective Date: 15.03.2017 RMT/1564/06 Effective Date: 18.01.2018	1 µg/mL to 15000 µg/mL

**Pooja Singh**  
Convenor

**Jitendra B. Vispute**  
Program Manager

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		Assay	RMT/1653/10 Effective Date: 01.02.2018 RMT/1187/04 Effective Date: 15.03.2017 RMT/1564/06 Effective Date: 18.01.2018	50% to 102%
3.	<b>Donepezil HCl</b>	Residual Solvents Tetrahydrofuran	RMT/676/07 Effective Date: 06.02.2018 RMT/2558/01 Effective Date: 07.08.2015 RMT/1753/05 Effective Date: 12.07.2017 RMT/2429/02 Effective Date: 12.07.2017	1 µg/mL to 15000µg/mL
		Tert-butyl methyl ether	RMT/676/07 Effective Date: 06.02.2018 RMT/2558/01 Effective Date: 07.08.2015 RMT/1753/05 Effective Date: 12.07.2017 RMT/2429/02 Effective Date: 12.07.2017	1 µg/mL to 15000 µg/mL
		Methanol	RMT/676/07 Effective Date: 06.02.2018 RMT/2558/01 Effective Date: 07.08.2015 RMT/1753/05 Effective Date: 12.07.2017 RMT/2429/02 Effective Date: 12.07.2017	1 µg/mL to 15000 µg/mL
		Ethyl acetate	RMT/676/07 Effective Date: 06.02.2018 RMT/2558/01	1 µg/mL to 15000 µg/mL

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			Effective Date: 07.08.2015 RMT/1753/05 Effective Date: 12.07.2017 RMT/2429/02 Effective Date: 12.07.2017	
		Methylene chloride	RMT/676/07 Effective Date: 06.02.2018 RMT/2558/01 Effective Date: 07.08.2015 RMT/1753/05 Effective Date: 12.07.2017 RMT/2429/02 Effective Date: 12.07.2017	1 µg/mL to 15000 µg/mL
		Assay	RMT/676/07 Effective Date: 06.02.2018 RMT/2558/01 Effective Date: 07.08.2015 RMT/1753/05 Effective Date: 12.07.2017 RMT/2429/02 Effective Date: 12.07.2017	98% to 102%
4.	Duloxetine HCl	Residual Solvents Ethyl acetate	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date: 10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03	1 µg/mL to 15000 µg/mL

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			Effective Date: 24.04.2018 RMT/2995/02	
		Methanol	Effective Date: 18.04.2018 RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date: 10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	1 µg/mL to 15000 µg/mL
		Dimethyl sulfoxide	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date: 10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02	1 µg/mL to 15000 µg/mL



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		Toluene	Effective Date: 18.04.2018 RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date: 10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	1 µg/mL to 15000 µg/mL
		Isopropyl alcohol	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date: 10.07.2018  RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	1 µg/mL to 15000 µg/mL

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		Benzene	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date:10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	1 µg/mL to15000 µg/mL
		Ethanol	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date:10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	1 µg/mL to15000 µg/mL

**Pooja Singh**  
Convenor

**Jitendra B. Vispute**  
Program Manager

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		Acetic acid	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date:10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	1 µg/mL to15000 µg/mL
		Methylene chloride	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date:10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	1 µg/mL to15000 µg/mL

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		Acetone	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date:10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	1 µg/mL to 15000 µg/mL
		Assay	RMT/699/06 Effective Date: 26.02.2018 RMT/2995/02 Effective Date: 18.04.2018 RMT/2331/02 Effective Date: 15.05.2013 RMT/2421/06 Effective Date:10.07.2018 RMT/2741/03 Effective Date: 21.02.2018 RMT/2742/01 Effective Date: 27.01.2016 RMT/2943/03 Effective Date: 24.04.2018 RMT/2995/02 Effective Date: 18.04.2018	80% to 102%

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5.	Alfuzosin HCl	<b>Residual Solvents</b> Acetone	RMT/1343/06 Effective Date: 06.06.2018 RMT/2533/04 Effective Date: 07.02.2018 RMT/2294/03 Effective Date: 20.02.2018	1 µg/mL to 15000 µg/mL
		Methanol	RMT/1343/06 Effective Date: 06.06.2018  RMT/2533/04 Effective Date: 07.02.2018 RMT/2294/03 Effective Date: 20.02.2018	1 µg/mL to 15000 µg/mL
		Isopropyl Alcohol	RMT/1343/06 Effective Date: 06.06.2018 RMT/2533/04 Effective Date: 07.02.2018 RMT/2294/03 Effective Date: 20.02.2018	1 µg/mL to 15000 µg/mL
		Methylene Chloride	RMT/1343/06 Effective Date: 06.06.2018 RMT/2533/04 Effective Date: 07.02.2018 RMT/2294/03 Effective Date: 20.02.2018	1 µg/mL to 15000 µg/mL
		Assay	RMT/1343/06 Effective Date: 06.06.2018 RMT/2533/04 Effective Date: 07.02.2018 RMT/2294/03 Effective Date: 20.02.2018	80% to 102%

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<b>D.</b>	<b>PHARMACEUTICAL FINISHED PRODUCT - SPECIFIC TESTS</b>			
1.	Anagrelide capsules	Assay and Content Uniformity	RLT/3271/04 Effective Date: 20.11.2017 CTP/1263/06 Effective Date: 27.07.2018	50% to 110%
		Dissolution	RLT/3271/04 Effective Date: 20.11.2017 CTP/1263/06 Effective Date: 27.07.2018	25% to 110%
2.	Apixaban Tablets	Assay	CTP/1420/03 Effective Date : 28.12.2017 CTP/1421/06 Effective Date : 19.05.2018	50% to 110%
		Dissolution	CTP/1420/03 Effective Date : 28.12.2017 CTP/1421/06 Effective Date : 19.05.2018	5% to 110%
3.	Ivabradine Tablets	Assay	RLT/3446/05 Effective Date : 18.01.2018 RLT/3447/05 Effective Date : 18.01.2018 CTP/1400/03 Effective Date : 19.01.2018	50% to 110%
		Dissolution	RLT/3446/05 Effective Date : 18.01.2018 RLT/3447/05 Effective Date : 18.01.2018 CTP/1400/03 Effective Date : 19.01.2018	20% to 110%
4.	Rivaroxaban Tablets	Assay	RLT/3283/03- Effective Date :08.02.2018 CTP/1273/04 Effective Date: 23.01.2018	50% to 110%

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			CTP/1274/03 Effective Date: 23.01.2018	
		Dissolution	RLT/3283/03- Effective Date :08.02.2018 CTP/1273/04 Effective Date: 23.01.2018 CTP/1274/03 Effective Date: 23.01.2018	25% to 110%
5.	<b>Lurasidone Tablets</b>	Assay	CTP/1066/06 Effective Date : 04.06.2018	50% to 105%
		Dissolution	CTP/1066/06 Effective Date : 04.06.2018	7% to 105%
6.	<b>Domperidone Tablets</b>	Assay	RLT/1787/01 Effective Date : 19.06.2013	50% to 110%
		Dissolution	RLT/1787/01 Effective Date: 19.06.2013	10% to 110%
7.	<b>Human Plasma</b>	Fluvoxamine	MS-004-00 Effective Date: 30.04.2011	1.000 ng/mL to 125.000 ng/mL
		Gliclazide	MS-007-02 Effective Date: 09.08.2013	20.000 ng/mL to 4000.000 ng/mL
		Ropinirole	MS-012-01 Effective Date: 05.08.2011	20.000 pg/mL to 2500.000 pg/mL
		Lamotrigine	MS-015-00 Effective Date: 13.05.2011	2.500 ng/mL to 800.000 ng/mL
		Glimepiride	BS-030-01 Effective Date: 30.04.2015	2.000 ng/mL to 600.000 ng/mL
		Metformin	BS-036-01 Effective Date: 30.05.2015	12.000 ng/mL to 2000.000 ng/mL
		Celecoxib	MS-032-01 Effective Date: 02.06.2012	10.000 ng/mL to 2000.000 ng/mL
		Moxifloxacin	MS-048-00 Effective Date: 18.05.2013	25.000 ng/mL to 4500.000 ng/mL

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		Citalopram	MS-050-00 Effective Date: 06.04.2012	0.500 ng/mL to 40.000 ng/mL
		Pregabalin	MS-054-01 Effective Date: 29.09.2012	60.000 ng/mL to 12000.000 ng/mL
		Citalopram	MS-058-00 Effective Date: 01.05.2013	0.500 ng/mL to 100.000 ng/mL
		Olmesartan	MS-063-00 Effective Date: 17.10.2013	30.000 ng/mL to 2000.000 ng/mL
		Lurasidone	MS-069-00 Effective Date: 10.04.2013	1.000 ng/mL to 200.000 ng/mL
		Cefixime	MS-072-00 Effective Date: 08.05.2013	0.050 µg/mL to 8.000 µg/mL
		Rasagiline	BS-038-01 Effective Date: 11.08.2015	0.050 ng/mL to 15.000 ng/mL
		Fluoxetine	MS-076-00 Effective Date: 14.11.2013	0.250 ng/mL to 50.000 ng/mL
		Carbamazepine	MS-099-00 Effective Date: 10.07.2014	25.000 ng/mL to 7000.000 ng/mL
		Roflumilast	BS-031-03 Effective Date: 14.08.2015	0.100 ng/mL to 20.000 ng/mL
		Cinacalcet	BS-017-01 Effective Date: 30.03.2015	0.250 ng/mL to 100.000 ng/mL
		Tadalafil	BS-032-01 Effective Date: 21.01.2016	5.000 ng/mL to 1000.000 ng/mL