



Laboratory: Nepal Research Foundation, Analytical Service Division,
Om Ashram, Birgunj, Nepal
Discipline: Chemical Testing
Certificate Number : CT-001/4

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Annexure 1

1. DRUGS & PHARMACEUTICALS					
A. Physical & Physico-chemical Methods					
Sl.	Product(s) / Material of test	Specific tests performed	* Test Method / Standard against which tests are performed	Range of Testing/ Limits of detection	Uncertainty of Measurement ⁺ (±) at Value (95% CL)
i)	Drugs & Pharmaceuticals (General Tests)	pH	IP 2022, A - 2.4.24 Pg.261 & 262	0.1 - 14	4.58 ± 0.02
			BP 2022, Pg. V-A289, Appendix VL & VM		
			USP 42 (2019), <791>, Pg. 6948		
ii)		Melting Point	IP 2022,A - 2.4.21 (Method I),Pg.254	55-300°C	81.2± 0.2°C
			BP 2022, Pg. V-A276 (Method I), Appendix VA		
			USP 42 (2019), <741>, Apparatus-I, Pg. 6905		
iii)		Optical rotation	IP 2022, A - 2.4.22 Pg. 257 – 258	- 89° to + 89°	+6.679 ± 0.017°
			BP 2022, Pg. V-A281 Appendix V G		

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			USP 42 (2019), <781>, Pg. 6926		
iv)	Specific optical rotation		IP 2022, A - 2.4.22 Pg. 257 & 258	- 999.99° to +999.99°	+66.58 ± 0.29°
			BP 2022, Pg. V-A311 Appendix V G		
			USP 42 (2019), <781>, Pg. 6926		
v)	Limit test for Heavy metals		IP 2022, A - 2.3.13, (Method A,C & D), Pg. 172 to 173	Qualitative	NA
			BP 2022, Pg. V-A311, (Method A, B & D), Appendix VII		
			USP 42 (2019), <231>, (Method I & II), Pg. 6145		
vi)	Limit test for chlorides		IP 2022, A - 2.3.12 Pg. 172	Qualitative	NA
			BP 2022, Pg. V-A310, (Method 2.4.4), Appendix VII		
			USP 42 (2019), <221>, Pg. 6562		
vii)	Limit test for Arsenic		IP 2022, A - 2.3.10 Pg. 172	Qualitative	NA
			BP 2022, Pg. V-A309, (Method A) Appendix VII		
viii)	Limit test for Iron		IP 2022, A - 2.3.14 Pg. 173	Qualitative	NA
			BP 2022, Pg. V-A314, (Method 2.4.9), Appendix VII		
			USP 42 (2019), <241>, Pg. 6575		

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ix)		Limit test for Lead	IP 2022, A - 2.3.15 Pg. 173-174	Qualitative	NA
			USP 42 (2019), <251>, Pg. 6575		
x)	Drugs & Pharmaceuticals (General Tests)	Limit test for Sulphates	IP 2022, A - 2.3.17 Pg. 174	Qualitative	NA
			BP 2022, Pg. V-A317, (Method 2.4.13), Appendix VIII B		
			USP 42 (2019), <221>, Pg. 6562		
xi)		Water (Method A)	IP 2022, A - 2.3.43 Pg.190 & 191	0.2 % to 30 %	12.04 ± 0.14 %
		Water (Method I A)	BP 2022, Pg. V-A 347, Appendix IX C		
		Water (Method I a)	USP 42 (2019), <921>, Pg. 7092-7093		
xii)		Disintegration Test(Tablets and Capsules)	IP 2022, A - 2.5.1 Pg.351-352	Qualitative Coated Tabs -NMT 30 min. Enteric coated- NMT 1 hr	NA
			BP 2022, Pg. V-A392 to V-A394 Appendix XIIA(Test A)		
			USP 42 (2019), < 701>, Pg. 6866		
xiii)		Uniformity of weight of Single Dose Preparation	IP 2022, A -2.5.3 Pg.360 and 361	0.05 to 5.00 g	179.57 ± 1.15 mg
		Uniformity of Weight (mass) (for tablets and Capsules)	BP 2022, Pg. V-A417, Appendix XII C		
		Weight variation of Dietary Supplements (for tablets and Capsules)	USP 42 (2019),<2091>, Pg. 8540-8541		
ix)		Friability of Uncoated Tablets	IP 2022, A-2.5.5 Pg. 364-365	Qualitative	NA
			BP 2022, Pg. V- A586,VA587 Appendix XVII G		

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			USP 42 (2019), Pg.8017		
x)		Identification by IR	IP 2022, 2.4.6 A, Pg. 178-180	Qualitative	NA
			BP 2022, Pg. V-A183(A) to VA 186, Appendix II A		
			USP 42 (2019), <197>, Pg. 6520-6521		

B.		Drug Substance (API)			
Sl.	Product(s) / Material of test	Specific tests performed	* Test Method / Standard against which tests are performed	Range of Testing/ Limits of detection	Uncertainty of Measurement+ (±) at Value
i)	Albendazole IP	Solubility	IP 2022, Pg. 265 & 1392	Qualitative	NA
		Identification A		Qualitative	NA
		Assay		98-102 %	99.41 ± 0.025 %
ii)	Albendazole BP	Solubility	BP 2022, Pg. I-89	Qualitative	NA
		Identification A		Qualitative	NA
iii)	Albendazole USP	Solubility	USP 42 (2019), Pg. 103 & 6211	Qualitative	NA
		Identification A		Qualitative	NA
iv)	Alprazolam IP	Solubility	IP 2022, Pg. 265 & 1402-1403	Qualitative	NA
		Identification A ,B, C		Qualitative	NA
		Related Substances		Qualitative	NA
v)	Alprazolam BP	Solubility	BP 2022, Pg. I-110	Qualitative	NA
		Identification B		Qualitative	NA
vi)	Alprazolam USP	Solubility	USP 42 (2019), Pg. 141 & 6211	Qualitative	NA
		Identification A		Qualitative	NA
vii)	Amlodipine Besylate IP	Solubility	IP 2022, Pg. 266 & 1446-1447	Qualitative	NA
		Identification A ,C		Qualitative	NA
		Related Substances B		Qualitative	NA
viii)	Amlodipine Besylate BP	Solubility	BP 2022, Pg. I-159	Qualitative	NA
		Identification		Qualitative	NA

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ix)	Amlodipine Besylate USP	Solubility	USP 42 (2019), Pg. 280-281 & 6212	Qualitative	NA
		Identification A		Qualitative	NA
		Related Compound (Test-2)		Qualitative	NA
x)	Atenolol IP	Solubility	IP 2022, Pg. 267 & 1529-1530	Qualitative	NA
		Identification A ,B		Qualitative	NA
		Related Substances		Qualitative	NA
		Assay		98.5 – 100.5 %	98.82 ± 0.29 %
xi)	Atenolol BP	Solubility	BP 2022, Pg.I-221 to I-222	Qualitative	NA
		Identification B,C		Qualitative	NA
		Assay		98.5 – 100.5 %	98.82 ± 0.29 %
xii)	Atenolol USP	Solubility	USP 42 (2019), Pg. 6214 & 401-402	Qualitative	NA
		Identification A ,B		Qualitative	NA
		Organic Impurities		Qualitative	NA
xiii)	Atorvastatin Calcium IP	Solubility	IP 2022, Pg. 267 & 1535-1536	Qualitative	NA
		Identification A		Qualitative	NA
		Related Substances		Qualitative	NA
xiv)	Atorvastatin Calcium BP	Solubility	BP 2022, Pg. I-225,	Qualitative	NA
		Identification A		Qualitative	NA
xv)	Atorvastatin Calcium USP	Solubility	USP 42 (2019), Pg. 6214 & 410	Qualitative	NA
		Identification A		Qualitative	NA
xvi)	Clonazepam IP	Solubility	IP 2022, Pg.272& 1924	Qualitative	NA
		Identification		Qualitative	NA
		Related Substances		Qualitative	NA
xvii)	Clonazepam BP	Solubility	BP 2022, Pg. I-629	Qualitative	NA
		Identification		Qualitative	NA
xviii)	Clonazepam USP	Solubility	USP 42 (2019), Pg. 6224 & 1076	Qualitative	NA
		Identification		Qualitative	NA
xix)	Enalapril Maleate IP	Solubility	IP 2022, Pg. 276 &	Qualitative	NA

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		Identification A & B	2226-2227	Qualitative	NA
		Related Substances		Qualitative	NA
xx)	Enalapril Maleate BP	Solubility	BP 2022, Pg. I-893	Qualitative	NA
		Identification		Qualitative	NA
xxi)	Enalapril Maleate USP	Solubility	USP 42 (2019), pg. 6229 & 1582	Qualitative	NA
		Identification A		Qualitative	NA
xxii)	Gliclazide IP	Solubility	IP 2022, Pg. 279 & 2474-2475	Qualitative	NA
		Identification		Qualitative	NA
		Assay		98.5 – 101%	99.54 ± 0.06 %
xxiii)	Gliclazide BP	Solubility	BP 2022, Pg. I-1172- 1173	Qualitative	NA
		Identification		Qualitative	NA
		Assay		98.5 – 101%	99.54 ± 0.06 %
xxiv)	Glimepiride IP	Solubility	IP 2022, Pg. 279 & 2476-2477	Qualitative	NA
		Identification		Qualitative	NA
		Related Substances		Qualitative	NA
xxv)	Glimepiride BP	Solubility	BP 2022, Pg. I-1172 to I-1173	Qualitative	NA
		Identification		Qualitative	NA
		Related Substances		Qualitative	NA
xxvi)	Glimepiride USP	Solubility	USP 42 (2019), Pg. 6234 & 2062-2063	Qualitative	NA
		Identification A		Qualitative	NA
		Organic Impurities		Qualitative	NA
xxvii)	Hydrochlorothiazide IP	Solubility	IP 2022, Pg. 279 & 2527-2528	Qualitative	NA
		Identification A, B		Qualitative	NA
		Acidity or Alkalinity		Qualitative	NA
		Related Substances		Qualitative	NA
xxviii)	Hydrochlorothiazide BP	Solubility	BP 2022, I-1254 to I-1255	Qualitative	NA
		Identification A, B		Qualitative	NA
		Acidity or Alkalinity		Qualitative	NA
xxix)	Hydrochlorothiazide USP	Solubility	USP 42 (2019), Pg. 6236 & 2170	Qualitative	NA
		Identification A		Qualitative	NA
xxx)	Losartan Potassium IP	Solubility	IP 2022, Pg. 282 & 2791-2792	Qualitative	NA
		Identification		Qualitative	NA
		Related Substances		Qualitative	NA

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xxxi)	Losartan Potassium BP	Solubility	BP 2022, Pg. II-149	Qualitative	NA
		Identification		Qualitative	NA
xxxii)	Losartan Potassium USP	Solubility	USP 42 (2019), pg. 6242 & 2635-2636	Qualitative	NA
		Identification		Qualitative	NA
		Organic Impurities		Qualitative	NA
xxxiii)	Metformin HCl IP	Solubility	IP 2022, Pg. 284 & 2874-2875	Qualitative	NA
		Related Substances		Qualitative	NA
xxxiv)	Metformin HCl BP	Solubility	BP 2022, Pg. II-250	Qualitative	NA
xxxv)	Metformin HCl USP	Solubility	USP 42 (2019), Pg. 6244	Qualitative	NA
xxxvi)	Pioglitazone HCl IP	Solubility	IP 2022, Pg. 289 & 3277-3278	Qualitative	NA
		Identification A ,B		Qualitative	NA
		Related Substances		Qualitative	NA
xxxvii)	Pioglitazone HCl BP	Solubility	BP 2022, II-631	Qualitative	NA
		Identification A ,B		Qualitative	NA
xxxviii)	Pioglitazone HCl USP	Solubility	USP 42 (2019), Pg. 6253 & 3525	Qualitative	NA
		Identification A ,B		Qualitative	NA
xxxix)	Telmisartan IP	Solubility	IP 2022, Pg. 294 & 3726-3727	Qualitative	NA
	Identification	Qualitative		NA	
	Related Substances	Qualitative		NA	
XL)	Telmisartan BP	Solubility	BP 2022,Pg. II-1085	Qualitative	NA
		Identification		Qualitative	NA
Xli)	Telmisartan USP	Solubility	USP 42 (2019), Pg. 6266 & 4205	Qualitative	NA
		Identification A		Qualitative	NA
C. Tablets					
i)	Albendazole Tablets IP	Identification B	IP 2022, Pg. 1393-1394	Qualitative	NA
		Assay		50-140% of Label claim	108.93 ± 0.76 %
ii)	Alprazolam Tablets IP	Identification	IP 2018, Pg. 1181-1182	Qualitative	NA
		Dissolution		50-120% of Label claim	87.43 ± 0.76 %
		Uniformity of content		50-125% of Average value	95.85 ± 0.04 %
		Assay		50-140% of Label claim	98.39 ± 0.04 %
iii)	Amlodipine Besylate	Identification	IP 2022, Pg. 1404-1405	Qualitative	NA

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	Tablets IP	Related Substances		Qualitative	NA
		Dissolution		50-120% of Label claim	99.88 ± 0.87 %
		Uniformity of content		50-125% of Average value	100.41 ± 1.90 %
		Assay		50-140% of Label claim	104.59 ± 1.31 %
iv)	Atenolol Tablets IP	Identification A	IP 2022, Pg. 1530-1531	Qualitative	NA
		Identification B		Qualitative	
		Assay		50-140% of Label claim	103.24 ± 0.09 %
v)	Atenolol Tablets BP	Identification A	BP 2022, Pg. III-182	Qualitative	NA
		Assay		50-140% of Label claim	103.24 ± 0.09 %
vi)	Atenolol Tablets USP	Identification A	USP 42 (2019), p. 403	Qualitative	NA
vii)	Atorvastatin Calcium Tablets IP	Identification	IP 2022, Pg. 1536-1537	Qualitative	NA
		Related Substances		Qualitative	NA
		Dissolution		50-120% of Label claim	93.57 ± 0.03 %
		Uniformity of content		50-125% of Average value	95.98 ± 1.87 %
		Assay		50-140% of Label claim	104.81 ± 0.05 %
viii)	Clonazepam Tablets IP	Identification	IP 2022, Pg. 1925-1927	Qualitative	NA
		Dissolution		50-120% of Label claim	95.01 ± 0.04 %
		Assay		50-140% of Label claim	96.85 ± 0.10 %
		Related Substances		Qualitative	NA
		Uniformity of content		50-125% of Average value	96.57 ± 0.12 %
ix)	Clonazepam Tablets USP	Identification	USP 42 (2019), Pg. 1077-1078	Qualitative	NA
		Dissolution		50-120% of Label claim	95.01 ± 0.04 %
x)	Enalapril Maleate Tablets IP	Identification	IP 2022, Pg. 2228	Qualitative	NA
		Dissolution		50-120% of Label claim	96.96 ± 0.38 %
		Uniformity of content		50-125% of Average value	97.97 ± 0.04 %
		Assay		50-140% of Label claim	102.97 ± 0.29 %
xi)	Gliclazide Tablets IP	Identification	IP 2022, Pg. 2475-2476	Qualitative	NA
		Dissolution		50-120% of Label claim	98.14 ± 2.44 %
xii)	Gliclazide Tablets BP	Identification	BP 2022, Pg. III-732-733	Qualitative	NA
		Dissolution		50-120% of Label claim	98.14 ± 2.44 %
xiii)	Glimipride Tablets IP	Identification	IP 2022, Pg. 2478-2479	Qualitative	NA

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		Related Substances		Qualitative	NA
		Dissolution		50-120% of Label claim	78.98 ± 1.54 %
		Assay		50-140% of Label claim	98.09 ± 2.22 %
		Uniformity of content		50-125% of Average value	98.09 ± 2.22 %
xiv)	Glimipride Tablets USP	Identification A	USP 42 (2019), Pg. 2064-2066	Qualitative	NA
		Organic Impurities		Qualitative	NA
		Dissolution (Test-1)		50-120% of Label claim	78.98 ± 1.54 %
		Assay		50-140% of Label claim	98.09 ± 2.22 %
xv)	Hydrochlorothiazide Tablets IP	Assay	IP 2022, Pg. 2529-2530	50-140% of Label claim	101.27 ± 0.28 %
		Dissolution		50-120% of Label claim	98.69 ± 0.51 %
xvi)	Hydrochlorothiazide Tablets BP	Related Substances	BP 2022, Pg. III-772	Qualitative	NA
		Assay		50-140% of Label claim	101.27 ± 0.28 %
xvii)	Hydrochlorothiazide & Losartan Potassium Tablets IP	Identification	IP 2022, Pg. 2794-2795	Qualitative	NA
		Dissolution			
		Hydrochlorothiazide		50-120% of Label claim	78.86 ± 1.84 %
		Losartan Potassium		50-120% of Label claim	85.38 ± 1.97 %
		Uniformity of content			
		Hydrochlorothiazide		50-125% of Average value	89.49 ± 0.28 %
		Losartan Potassium		50-125% of Average value	108.19 ± 0.93 %
		Assay			
		Hydrochlorothiazide		50-140% of Label claim	101.04 ± 2.33 %
		Losartan Potassium	50-140% of Label claim	107.44 ± 3.76 %	
xviii)	Losartan Potassium Tablets IP	Identification	IP 2022, Pg. 2792-2793	Qualitative	NA
		Related Substances		Qualitative	NA
		Dissolution		50-120% of Label claim	97.21 ± 2.41 %
		Assay		50-140% of Label claim	99.91 ± 1.01 %
xix)	Metformin HCl Tablets IP	Identification A	IP 2022, Pg. 2878-2879	Qualitative	NA
		Dissolution		50-120% of Label claim	99.94±1.86 %
		Assay		50-140% of Label claim	98.93 ± 0.41 %

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		Related Substances		Qualitative	NA
xx)	Metformin HCl Tablets BP	Identification A	BP 2022, Pg. III-969 to III-970	Qualitative	NA
		Dissolution		50-120% of Label claim	99.94±1.86 %
		Assay		50-140% of Label claim	98.93 ± 0.41 %
xxi)	Pioglitazone HCl Tablets IP	Identification A & B	IP 2022, Pg. 3278-3279	Qualitative	NA
		Related Substances		Qualitative	NA
		Dissolution		50-120% of Label claim	97.04 ± 2.27 %
		Assay		50-140% of Label claim	98.82 ± 2.31 %
xxii)	Propranolol Tablets IP	Identification A & B	IP 2022, Pg. 3380-3381	Qualitative	NA
		Assay		50-140% of Label claim	99.04 ± 0.57 %
		Dissolution		50-120% of Label claim	102.84± 0.67 %
		Uniformity of content		50-125% of Average value	105.82 ± 0.58 %
		Related Substances		Qualitative	NA
xxiii)	Propranolol Tablets BP	Identification	BP 2022, Pg. III-1243 to III-1244	Qualitative	NA
		Assay		50-140% of Label claim	99.04 ± 0.57 %
xxiv)	Rosuvastatin Tablets IP	Identification	IP 2022, Pg. 3529-3530	Qualitative	NA
		Related Substances		Qualitative	NA
		Dissolution		50-120% of Label claim	71.38 ± 0.44 %
		Uniformity of content		50-125% of Average value	108.04 ± 0.13 %
		Assay		50-140% of Label claim	107.31 ± 0.25 %
xxv)	Telmisartan Tablets IP	Identification	IP 2022, Pg. 3727-3728	Qualitative	NA
		Related Substances		Qualitative	NA
		Assay		50-140% of Label claim	99.53 ± 2.26 %
		Dissolution		50-120% of Label claim	94.52 ± 2.48 %
xxvi)	Telmisartan Tablets USP	Dissolution	USP 42 (2019), Pg. 4207	50-120% of Label claim	94.52 ± 2.48 %



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