AERSSC

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Annexure

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**	
i)	Drugs & Pharmaceuticals (General Tests)	pH	IP 2018, A - 2.4.24 Pg.215 & 216 BP 2019, Pg. V-A278, Appendix V K USP 42 (2019), <791>, Pg. 6948	0.1 – 14	
ii)		Melting Point	IP 2018,A - 2.4.21 (Method I),Pg.209-210 BP 2019, Pg. V-A265 A(Method I), Appendix VA USP 42 (2019), <741>, Apparatus-I, Pg. 6905	55-300˚C	
iii)		Optical rotation	IP 2018, A - 2.4.22 Pg. 212 – 214 BP 2019, Pg. V-A270 Appendix V E USP 42 (2019), <781>, Pg. 6926	- 89˚ to + 89˚	
iv)		Specific optical rotation	IP 2018, A - 2.4.22 Pg. 212 & 214	- 999.99˚ to +999.99˚	

			BP 2019, Pg. V-A270 Appendix V E		
			USP 42 (2019), <781>, Pg. 6926		
v)		Limit test for Heavy metals	IP 2018, A - 2.3.13, (Method A,C & D), Pg. 139	Qualitative	
			BP 2019, Pg. V-A299, (Method A, B & D), Appendix VII		
			USP 42 (2019), <231>, (Method I & II), Pg. 6145		
vi)		Limit test for chlorides	IP 2018, A - 2.3.12 Pg. 138-139	Qualitative	
			BP 2019, Pg. V-A298, (Method 2.4.4), Appendix VII		
			USP 42 (2019), <221>, Pg. 6562		
vii)		Limit test for Arsenic	IP 2018, A - 2.3.10 Pg. 138	Qualitative	
			BP 2019, Pg. V-A297, (Method A) Appendix VII		
viii)		Limit test for Iron	IP 2018, A - 2.3.14 Pg. 139	Qualitative	
			BP 2019, Pg. V-A302, (Method 2.4.9), Appendix VII		
			USP 42 (2019), <241>, Pg. 6575		
ix)		Limit test for Lead	IP 2018, A - 2.3.15 Pg. 139-140	Qualitative	
			USP 42 (2019), <251>, Pg. 6575		
x)	Drugs & Pharmaceuticals (General Tests)	Limit test for Sulphates	IP 2018, A - 2.3.17 Pg. 140	Qualitative	
			BP 2019, Pg.V-A305, (Method 2.4.13), Appendix VIII		

			USP 42 (2019), <221>, Pg. 6562		
xi)		Water (Method A)	IP 2018, A - 2.3.43 Pg.156 158	0.002 % to 100 %	
		Water (Method I A)	BP 2019, Pg. V-A 335, Appendix IX C		
		Water (Method I a)	USP 42 (2019), <921>, Pg. 7092-7093		
xii)		Disintegration Test(Tablets and Capsules)	IP 2018, A - 2.5.1 Pg.299-302	Qualitative Coated Tabs -NMT 30 min. Enteric coated- NMT 1 hr	
			BP 2019, Pg. V-A378 Appendix XIIA(Test A)		
			USP 42 (2019), < 701>, Pg. 6866		
xiii)		Uniformity of weight of Single Dose Preparation	IP 2018, A -2.5.3 Pg.308	0.05 to 5.00 g	
		Uniformity of Weight (mass) (for tablets and Capsules)	BP 2019, Pg. V-A402 to V-A403, 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 2018, A-2.5.5 Pg. 309	Qualitative	
			BP 2019, Pg. V-A558 Appendix XVII G		
			USP 42 (2019), Pg.8017		
x)		Identification by IR	IP 2018, 2.4.6 A, Pg. 178-180	Qualitative	
			BP 2019, Pg. V-A181(A), 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**	
i)	Albendazole IP	Solubility	IP 2018, Pg. 220 & 1168-1169	Qualitative	
		Identification A		Qualitative	
		Assay		98-102 %	
ii)	Albendazole BP	Solubility	BP 2019, Pg. I-88	Qualitative	
		Identification A		Qualitative	
iii)	Albendazole USP	Solubility	USP 42 (2019), Pg. 103 & 6211	Qualitative	
		Identification A		Qualitative	
iv)	Alprazolam IP	Solubility	IP 2018, Pg. 221 & 1180-1181	Qualitative	
		Identification A ,B, C		Qualitative	
		Related Substances		Qualitative	
v)	Alprazolam BP	Solubility	BP 2019, Pg. I-107	Qualitative	
		Identification B		Qualitative	
vi)	Alprazolam USP	Solubility	USP 42 (2019), Pg. 141 & 6211	Qualitative	
		Identification A		Qualitative	
vii)	Amlodipine Besylate IP	Solubility	IP 2018, Pg. 221 & 1219-1220	Qualitative	
		Identification A ,C		Qualitative	
		Related Substances B		Qualitative	
viii)	Amlodipine Besylate BP	Solubility	BP 2019, Pg. I-156	Qualitative	
		Identification		Qualitative	
ix)	Amlodipine Besylate USP	Solubility	USP 42 (2019), Pg. 280-281 & 6212	Qualitative	
		Identification A		Qualitative	
		Related Compound (Test-2)		Qualitative	
x)	Atenolol IP	Solubility	IP 2018, Pg. 222 & 1281-1282	Qualitative	
		Identification A ,B		Qualitative	
		Related Substances		Qualitative	
		Assay		98.5 – 100.5 %	
xi)	Atenolol BP	Solubility	BP 2019, Pg.I-214 to I-215	Qualitative	
		Identification B,C		Qualitative	
		Assay		98.5 – 100.5 %	
xii)	Atenolol USP	Solubility	USP 42 (2019), Pg. 6214 & 401-402	Qualitative	
		Identification A ,B		Qualitative	
		Organic Impurities		Qualitative	

xiii)	Atorvastatin Calcium IP	Solubility	IP 2018, Pg. 222 & 1286-1287	Qualitative	
		Identification A		Qualitative	
		Related Substances		Qualitative	
xiv)	Atorvastatin Calcium BP	Solubility	BP 2019, Pg. I-218,	Qualitative	
		Identification A		Qualitative	
xv)	Atorvastatin Calcium USP	Solubility	USP 42 (2019), Pg. 6214 & 410	Qualitative	
		Identification A		Qualitative	
xvi)	Clonazepam IP	Solubility	IP 2018, Pg.227& 1669	Qualitative	
		Identification		Qualitative	
		Related Substances		Qualitative	
xvii)	Clonazepam BP	Solubility	BP 2019, Pg. I-625	Qualitative	
		Identification		Qualitative	
xviii)	Clonazepam USP	Solubility	USP 42 (2019), Pg. 6224 & 1076	Qualitative	
		Identification		Qualitative	
xix)	Enalapril Maleate IP	Solubility	IP 2018, Pg. 231 & 1938-1940	Qualitative	
		Identification A & B		Qualitative	
		Related Substances		Qualitative	
xx)	Enalapril Maleate BP	Solubility	BP 2019, Pg. I-886	Qualitative	
		Identification		Qualitative	
xxi)	Enalapril Maleate USP	Solubility	USP 42 (2019), pg. 6229 & 1582	Qualitative	
		Identification A		Qualitative	
xxii)	Gliclazide IP	Solubility	IP 2018, Pg. 234 & 2175-2176	Qualitative	
		Identification		Qualitative	
		Assay		98.5 – 101%	
xxiii)	Gliclazide BP	Solubility	BP 2019, Pg. I-1156	Qualitative	
		Identification		Qualitative	
		Assay		98.5 – 101%	
xxiv)	Glimepiride IP	Solubility	IP 2018, Pg. 234 & 2177-2178	Qualitative	
		Identification		Qualitative	
		Related Substances		Qualitative	
xxv)	Glimepiride BP	Solubility	BP 2019, Pg. I-1157 to I-1158	Qualitative	
		Identification		Qualitative	
		Related Substances		Qualitative	
xxvi)	Glimepiride USP	Solubility	USP 42 (2019), Pg. 6234 & 2062-2063	Qualitative	
		Identification A		Qualitative	
		Organic Impurities		Qualitative	

xxvii)	Hydrochlorothiazide IP	Solubility	IP 2018, Pg. 234 & 2218-2220	Qualitative	
		Identification A, B		Qualitative	
		Identification A			
		Acidity or Alkalinity		Qualitative	
		Related Substances		Qualitative	
xxviii)	Hydrochlorothiazide BP	Solubility	BP 2019, I-1240 to I-1241	Qualitative	
		Identification A, B		Qualitative	
		Acidity or Alkalinity		Qualitative	
xxix)	Hydrochlorothiazide USP	Solubility	USP 42 (2019), Pg. 6236 & 2170	Qualitative	
		Identification A		Qualitative	
xxx)	Losartan Potassium IP	Solubility	IP 2018, Pg. 237 & 2467-2468	Qualitative	
		Identification		Qualitative	
		Related Substances		Qualitative	
xxxi)	Losartan Potassium BP	Solubility	BP 2019, Pg. II-142	Qualitative	
		Identification		Qualitative	
xxxii)	Losartan Potassium USP	Solubility	USP 42 (2019), pg. 6242 & 2635-2636	Qualitative	
		Identification		Qualitative	
		Organic Impurities		Qualitative	
xxxiii)	Metformin HCl IP	Solubility	IP 2018, Pg. 238 & 2544-2545	Qualitative	
		Related Substances		Qualitative	
xxxiv)	Metformin HCl BP	Solubility	BP 2019, Pg. II-238	Qualitative	
xxxv)	Metformin HCl USP	Solubility	USP 42 (2019), Pg. 6244	Qualitative	
xxxvi)	Pioglitazone HCl IP	Solubility	IP 2018, Pg. 243 & 2933	Qualitative	
		Identification A ,B		Qualitative	
		Related Substances		Qualitative	
xxxvii)	Pioglitazone HCl BP	Solubility	BP 2019, II-614	Qualitative	
		Identification A ,B		Qualitative	
xxxviii)	Pioglitazone HCl USP	Solubility	USP 42 (2019), Pg. 6253 & 3525	Qualitative	
		Identification A ,B		Qualitative	
xxxix)	Telmisartan IP	Solubility	IP 2018, Pg. 248 & 3319-3320	Qualitative	
		Identification		Qualitative	
		Related Substances		Qualitative	
XL)	Telmisartan BP	Solubility	BP 2019,Pg. II-1048 to II-1049	Qualitative	
		Identification		Qualitative	
Xli)	Telmisartan USP	Solubility	USP 42 (2019), Pg. 6266 & 4205	Qualitative	
		Identification A		Qualitative	

C.	**Tablets**				
i)	Albendazole Tablets IP	Identification B	IP 2018, Pg. 1170	Qualitative	
		Assay		50-140% of Label claim	
ii)	Alprazolam Tablets IP	Identification	IP 2018, Pg. 1181-1182	Qualitative	
		Dissolution		50-120% of Label claim	
		Uniformity of content		50-125% of Average value	
		Assay		50-140% of Label claim	
iii)	Amlodipine Besylate Tablets IP	Identification	IP 2018, Pg. 1220-1221	Qualitative	
		Related Substances		Qualitative	
		Dissolution		50-120% of Label claim	
		Uniformity of content		50-125% of Average value	
		Assay		50-140% of Label claim	
iv)	Atenolol Tablets IP	Identification A	IP 2018, Pg. 1282-1283	Qualitative	
		Identification B		Qualitative	
		Assay		50-140% of Label claim	
v)	Atenolol Tablets BP	Identification A	BP 2019, Pg. III-172-III-173	Qualitative	
		Identification B		Qualitative	
		Assay		50-140% of Label claim	
vi)	Atenolol Tablets USP	Identification A	USP 42 (2019), p. 403	Qualitative	
vii)	Atorvastatin Calcium Tablets IP	Identification	IP 2018, Pg. 1287-1288	Qualitative	
		Related Substances		Qualitative	
		Dissolution		50-120% of Label claim	
		Uniformity of content		50-125% of Average value	
		Assay		50-140% of Label claim	
viii)	Clonazepam Tablets IP	Identification	IP 2018, Pg. 1287-1288	Qualitative	
		Dissolution		50-120% of Label claim	
		Assay		50-140% of Label claim	
		Related Substances		Qualitative	
		Uniformity of content		50-125% of Average value	
ix)	Clonazepam Tablets USP	Identification	USP 42 (2019), Pg. 1077-1078	Qualitative	
		Dissolution		50-120% of Label claim	
x)	Enalapril Maleate Tablets IP	Identification	IP 2018, Pg. 1940	Qualitative	
		Dissolution		50-120% of Label claim	
		Uniformity of content		50-125% of Average value	
		Assay		50-140% of Label claim	
xi)	Gliclazide Tablets IP	Identification	IP 2018, Pg. 2176	Qualitative	

		Dissolution		50-120% of Label claim	
xii)	Gliclazide Tablets BP	Identification	BP 2019, Pg. III-690	Qualitative	
		Dissolution		50-120% of Label claim	
xiii)	Glimipride Tablets IP	Identification	IP 2018, Pg. 2179	Qualitative	
		Related Substances		Qualitative	
		Dissolution		50-120% of Label claim	
		Assay		50-140% of Label claim	
		Uniformity of content		50-125% of Average value	
xiv)	Glimipride Tablets USP	Identification A	USP 42 (2019), Pg. 2064-2066	Qualitative	
		Organic Impurities		Qualitative	
		Dissolution (Test-1)		50-120% of Label claim	
		Assay		50-140% of Label claim	
xv)	Hydrochlorothiazide Tablets IP	Related Substances	IP 2018, Pg. 2220-2221	Qualitative	
		Assay		50-140% of Label claim	
		Dissolution		50-120% of Label claim	
xvi)	Hydrochlorothiazide Tablets BP	Related Substances	BP 2019, Pg. III-725 to III-726	Qualitative	
		Assay		50-140% of Label claim	
xvii)	Hydrochlorothiazide & Losartan Potassium Tablets IP	Identification	IP 2018, Pg. 2470-2471	Qualitative	
		Dissolution			
		Hydrochlorothiazide		50-120% of Label claim	
		Losartan Potassium		50-120% of Label claim	
		Uniformity of content			
		Hydrochlorothiazide		50-125% of Average value	
		Losartan Potassium		50-125% of Average value	
		Assay			
		Hydrochlorothiazide		50-140% of Label claim	
		Losartan Potassium		50-140% of Label claim	
xviii)	Losartan Potassium Tablets IP	Identification	IP 2018, Pg. 2468-2469	Qualitative	
		Related Substances		Qualitative	
		Dissolution		50-120% of Label claim	
		Assay		50-140% of Label claim	
xix)	Metformin HCl Tablets IP	Identification A	IP 2018, Pg. 2548	Qualitative	
		Dissolution		50-120% of Label claim	
		Assay		50-140% of Label claim	
		Related Substances		Qualitative	
xx)	Metformin HCl Tablets BP	Identification A	BP 2019, Pg. III-911 to	Qualitative	

		Dissolution	III-912	50-120% of Label claim	
		Assay		50-140% of Label claim	
xxi)	Pioglitazone HCl Tablets IP	Identification A & B	IP 2018, Pg. 2933-2934	Qualitative	
		Related Substances		Qualitative	
		Dissolution		50-120% of Label claim	
		Assay		50-140% of Label claim	
xxii)	Propranolol Tablets IP	Identification A & B	IP 2018, Pg. 3024-3025	Qualitative	
		Assay		50-140% of Label claim	
		Dissolution		50-120% of Label claim	
		Uniformity of content		50-125% of Average value	
		Related Substances		Qualitative	
xxiii)	Propranolol Tablets BP	Identification A & B	BP 2019, Pg. III-1163 to III-1164	Qualitative	
		Assay		50-140% of Label claim	
xxiv)	Rosuvastatin Tablets IP	Identification	IP 2018, Pg. 3142-3143	Qualitative	
		Related Substances		Qualitative	
		Dissolution		50-120% of Label claim	
		Uniformity of content		50-125% of Average value	
		Assay		50-140% of Label claim	
xxv)	Telmisartan Tablets IP	Identification	IP 2018, Pg. 3320-3321	Qualitative	
		Related Substances		Qualitative	
		Assay		50-140% of Label claim	
		Dissolution		50-120% of Label claim	
xxvi)	Telmisartan Tablets USP	Dissolution	USP 42 (2019), Pg. 4207	50-120% of Label claim