

MANIPAL UNIVERSITY

PHARM. PART-I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601)

SPECIALIZATION: PHARMACEUTICS/INDUSTRIAL PHARMACY/PHARM. QUALITY ASSURANCE/PHARM. BIOTECHNOLOGY

Saturday, May 24, 2014

Time: 10:00 – 13:00 Hrs.

Max. Marks: 100

Answer ALL questions.

- 1A. Explain the construction and working of gratings.
 1B. Explain the merits and demerits of phosphorimetry over fluorimetry.
 1C. Write a note on formation of LASER.
 1D. Explain the principle and experimental requirements for ELISA.
- (5 marks × 4 = 20 marks)

- 2A. Explain the different paper electrophoresis methods in brief.
 2B. List the applications of capillary zone electrophoresis.
 2C. Name the applications of Raman Spectroscopy.
 2D. Describe the working principles of 'thermal detectors' employed in IR spectrometer.
- (5 marks × 4 = 20 marks)

- 3A. Describe the simplification of complex in proton NMR spectra.
 3B. Write a note in 2-D NMR.
 3C. Explain the principle of chemical ionization and field desorption mass spectrometry.
 3D. What is metastable ion? Explain with suitable example.
- (5 marks × 4 = 20 marks)

- 4A. Explain LC-MS Interfaces.
 4B. With the help of van Deemter equation, explain how band broadening can be reduced.
 4C. Explain how *in-situ* densitometer can be used for quantitative analysis in HPTLC?
 4D. What is temperature programming in GC? Discuss its advantages and disadvantages. Discuss the Giddings equation.
- (5 marks × 4 = 20 marks)

- 5A. Explain in brief the 'single point direct comparison method' for quantitative analysis in GC. An injection containing benzene at a concentration of 2000 µgm/ml is made and results in a peak area of 100000. An injection with an unknown concentration of benzene has a peak area of 57,000. Calculate the amount of benzene present.
 5B. Discuss degassing in HPLC and its importance. Explain various methods of degassing.
 5C. Compare the sensitivity, specificity and applications of any four HPLC detectors.
 5D. Write the principle, types of stationary phases used, advantages and applications of gel permeation chromatography.
- (5 marks × 4 = 20 marks)



MANIPAL UNIVERSITY

M. PHARM. PART-I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602)
(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE / DRUG REGULATORY AFFAIRS)

Monday, May 26, 2014

Time: 10:00 – 13:00 Hrs.

Max. Marks: 100

✍ **Answer ALL questions.**

✍ **Scientific calculators are allowed.**

1A. Write in detail about location, design, plant layout, construction of the pharmaceutical manufacturing facility.

1B. Write in brief personnel responsibility, training and hygiene for the pharmaceutical industry.
(10+10 = 20 marks)

2A. What is ISO 9000 and 14000? Explain in detail.

2B. Define Standard Operating Procedure (SOP). Enlist components of SOP.
(15+5 = 20 marks)

3A. Explain the analytical method validation as per ICH guidelines.

3B. Explain QUEST approach for vendor validation.
(10+10 = 20 marks)

4A. In an ophthalmic OPD 170 persons above 40 years were examined. 40 had both trachoma and corneal degeneration while 34 had none. Total cases of corneal degeneration obtained were 101. Determine if there is any association between trachoma and corneal degeneration. Justify your answer with suitable statistical hypothesis.

	Trachoma	No Trachoma	Total
Corneal degeneration	40	61	101
No Corneal degeneration	35	34	69
Total	75	95	170

4B. What is quality audit? Explain different types in brief.

4C. Write a note on good Warehouse practice.
(10+5+5 = 20 marks)

5A. Write in short about the packaging and labeling control.

5B. Write in brief on complaints and recall.

5C. What is the importance of control on reserve samples? Explain.
(8+7+5 = 20 marks)



DF	0.995	0.975	0.20	0.10	0.05	0.025	0.02	0.01	0.005	0.002	0.001
1	0.0000393	0.000982	1.642	2.706	3.841	5.024	5.412	6.635	7.879	9.550	10.828
2	0.0100	0.0506	3.219	4.605	5.991	7.378	7.824	9.210	10.597	12.429	13.816
3	0.0717	0.216	4.642	6.251	7.815	9.348	9.837	11.345	12.838	14.796	16.266
4	0.207	0.484	5.989	7.779	9.488	11.143	11.668	13.277	14.860	16.924	18.467
5	0.412	0.831	7.289	9.236	11.070	12.833	13.388	15.086	16.750	18.907	20.515
6	0.676	1.237	8.558	10.645	12.592	14.449	15.033	16.812	18.548	20.791	22.458
7	0.989	1.690	9.803	12.017	14.067	16.013	16.622	18.475	20.278	22.601	24.322
8	1.344	2.180	11.030	13.362	15.507	17.535	18.168	20.090	21.955	24.352	26.124
9	1.735	2.700	12.242	14.684	16.919	19.023	19.679	21.666	23.589	26.056	27.877
10	2.156	3.247	13.442	15.987	18.307	20.483	21.161	23.209	25.188	27.722	29.588
11	2.603	3.816	14.631	17.275	19.675	21.920	22.618	24.725	26.757	29.354	31.264
12	3.074	4.404	15.812	18.549	21.026	23.337	24.054	26.217	28.300	30.957	32.909
13	3.565	5.009	16.985	19.812	22.362	24.736	25.472	27.688	29.819	32.535	34.528
14	4.075	5.629	18.151	21.064	23.685	26.119	26.873	29.141	31.319	34.091	36.123
15	4.601	6.262	19.311	22.307	24.996	27.488	28.259	30.578	32.801	35.628	37.697
16	5.142	6.908	20.465	23.542	26.296	28.845	29.633	32.000	34.267	37.146	39.252
17	5.697	7.564	21.615	24.769	27.587	30.191	30.995	33.409	35.718	38.648	40.790
18	6.265	8.231	22.760	25.989	28.869	31.526	32.346	34.805	37.156	40.136	42.312
19	6.844	8.907	23.900	27.204	30.144	32.852	33.687	36.191	38.582	41.610	43.820
20	7.434	9.591	25.038	28.412	31.410	34.170	35.020	37.566	39.997	43.072	45.315
21	8.034	10.283	26.171	29.615	32.671	35.479	36.343	38.932	41.401	44.522	46.797
22	8.643	10.982	27.301	30.813	33.924	36.781	37.659	40.289	42.796	45.962	48.268
23	9.260	11.689	28.429	32.007	35.172	38.076	38.968	41.638	44.181	47.391	49.728
24	9.886	12.401	29.553	33.196	36.415	39.364	40.270	42.980	45.559	48.812	51.179
25	10.520	13.120	30.675	34.382	37.652	40.646	41.566	44.314	46.928	50.223	52.620
26	11.160	13.844	31.795	35.563	38.885	41.923	42.856	45.642	48.290	51.627	54.052
27	11.808	14.573	32.912	36.741	40.113	43.195	44.140	46.963	49.645	53.023	55.476
28	12.461	15.308	34.027	37.916	41.337	44.461	45.419	48.278	50.993	54.411	56.892
29	13.121	16.047	35.139	39.087	42.557	45.722	46.693	49.588	52.336	55.792	58.301
30	13.787	16.791	36.250	40.256	43.773	46.979	47.962	50.892	53.672	57.167	59.703
31	14.458	17.539	37.359	41.422	44.985	48.232	49.226	52.191	55.003	58.536	61.098
32	15.134	18.291	38.466	42.585	46.194	49.480	50.487	53.486	56.328	59.899	62.487
33	15.815	19.047	39.572	43.745	47.400	50.725	51.743	54.776	57.648	61.256	63.870
34	16.501	19.806	40.676	44.903	48.602	51.966	52.995	56.061	58.964	62.608	65.247
35	17.192	20.569	41.778	46.059	49.802	53.203	54.244	57.342	60.275	63.955	66.619
36	17.887	21.336	42.879	47.212	50.998	54.437	55.489	58.619	61.581	65.296	67.985
37	18.586	22.106	43.978	48.363	52.192	55.668	56.730	59.893	62.883	66.633	69.346
38	19.289	22.878	45.076	49.513	53.384	56.896	57.969	61.162	64.181	67.966	70.703
39	19.996	23.654	46.173	50.660	54.572	58.120	59.204	62.428	65.476	69.294	72.055
40	20.707	24.433	47.269	51.805	55.758	59.342	60.436	63.691	66.766	70.618	73.402
41	21.421	25.215	48.363	52.949	56.942	60.561	61.665	64.950	68.053	71.938	74.745
42	22.138	25.999	49.456	54.090	58.124	61.777	62.892	66.206	69.336	73.254	76.084
43	22.859	26.785	50.548	55.230	59.304	62.990	64.116	67.459	70.616	74.566	77.419
44	23.584	27.575	51.639	56.369	60.481	64.201	65.337	68.710	71.893	75.874	78.750
45	24.311	28.366	52.729	57.505	61.656	65.410	66.555	69.957	73.166	77.179	80.077
46	25.041	29.160	53.818	58.641	62.830	66.617	67.771	71.201	74.437	78.481	81.400
47	25.775	29.956	54.906	59.774	64.001	67.821	68.985	72.443	75.704	79.780	82.720
48	26.511	30.755	55.993	60.907	65.171	69.023	70.197	73.683	76.969	81.075	84.037
49	27.249	31.555	57.079	62.038	66.339	70.222	71.406	74.919	78.231	82.367	85.351
50	27.991	32.357	58.164	63.167	67.505	71.420	72.613	76.154	79.490	83.657	86.661
51	28.735	33.162	59.248	64.295	68.669	72.616	73.818	77.386	80.747	84.943	87.968
52	29.481	33.968	60.332	65.422	69.832	73.810	75.021	78.616	82.001	86.227	89.272
53	30.230	34.776	61.414	66.548	70.993	75.002	76.223	79.843	83.253	87.507	90.573
54	30.981	35.586	62.496	67.673	72.153	76.192	77.422	81.069	84.502	88.786	91.872
55	31.735	36.398	63.577	68.796	73.311	77.380	78.619	82.292	85.749	90.061	93.168
56	32.490	37.212	64.658	69.919	74.468	78.567	79.815	83.513	86.994	91.335	94.461
57	33.248	38.027	65.737	71.040	75.624	79.752	81.009	84.733	88.236	92.605	95.751
58	34.008	38.844	66.816	72.160	76.778	80.936	82.201	85.950	89.477	93.874	97.039

59	34.770	39.662	67.894	73.279	77.931	82.117	83.391	87.166	90.715	95.140	98.31
60	35.534	40.482	68.972	74.397	79.082	83.298	84.580	88.379	91.952	96.404	99.60
61	36.301	41.303	70.049	75.514	80.232	84.476	85.767	89.591	93.186	97.665	100.81
62	37.068	42.126	71.125	76.630	81.381	85.654	86.953	90.802	94.419	98.925	102.16
63	37.838	42.950	72.201	77.745	82.529	86.830	88.137	92.010	95.649	100.182	103.44
64	38.610	43.776	73.276	78.860	83.675	88.004	89.320	93.217	96.878	101.437	104.71
65	39.383	44.603	74.351	79.973	84.821	89.177	90.501	94.422	98.105	102.691	105.98
66	40.158	45.431	75.424	81.085	85.965	90.349	91.681	95.626	99.330	103.942	107.25
67	40.935	46.261	76.498	82.197	87.108	91.519	92.860	96.828	100.554	105.192	108.52
68	41.713	47.092	77.571	83.308	88.250	92.689	94.037	98.028	101.776	106.440	109.791
69	42.494	47.924	78.643	84.418	89.391	93.856	95.213	99.228	102.996	107.685	111.055
70	43.275	48.758	79.715	85.527	90.531	95.023	96.388	100.425	104.215	108.929	112.317
71	44.058	49.592	80.786	86.635	91.670	96.189	97.561	101.621	105.432	110.172	113.577
72	44.843	50.428	81.857	87.743	92.808	97.353	98.733	102.816	106.648	111.412	114.835
73	45.629	51.265	82.927	88.850	93.945	98.516	99.904	104.010	107.862	112.651	116.092
74	46.417	52.103	83.997	89.956	95.081	99.678	101.074	105.202	109.074	113.889	117.346
75	47.206	52.942	85.066	91.061	96.217	100.839	102.243	106.393	110.286	115.125	118.599
76	47.997	53.782	86.135	92.166	97.351	101.999	103.410	107.583	111.495	116.359	119.850
77	48.788	54.623	87.203	93.270	98.484	103.158	104.576	108.771	112.704	117.591	121.100
78	49.582	55.466	88.271	94.374	99.617	104.316	105.742	109.958	113.911	118.823	122.348
79	50.376	56.309	89.338	95.476	100.749	105.473	106.906	111.144	115.117	120.052	123.594
80	51.172	57.153	90.405	96.578	101.879	106.629	108.069	112.329	116.321	121.280	124.839
81	51.969	57.998	91.472	97.680	103.010	107.783	109.232	113.512	117.524	122.507	126.083
82	52.767	58.845	92.538	98.780	104.139	108.937	110.393	114.695	118.726	123.733	127.324
83	53.567	59.692	93.604	99.880	105.267	110.090	111.553	115.876	119.927	124.957	128.565
84	54.368	60.540	94.669	100.980	106.395	111.242	112.712	117.057	121.126	126.179	129.804
85	55.170	61.389	95.734	102.079	107.522	112.393	113.871	118.236	122.325	127.401	131.041
86	55.973	62.239	96.799	103.177	108.648	113.544	115.028	119.414	123.522	128.621	132.277
87	56.777	63.089	97.863	104.275	109.773	114.693	116.184	120.591	124.718	129.840	133.512
88	57.582	63.941	98.927	105.372	110.898	115.841	117.340	121.767	125.913	131.057	134.745
89	58.389	64.793	99.991	106.469	112.022	116.989	118.495	122.942	127.106	132.273	135.978
90	59.196	65.647	101.054	107.565	113.145	118.136	119.648	124.116	128.299	133.489	137.208
91	60.005	66.501	102.117	108.661	114.268	119.282	120.801	125.289	129.491	134.702	138.438
92	60.815	67.356	103.179	109.756	115.390	120.427	121.954	126.462	130.681	135.915	139.666
93	61.625	68.211	104.241	110.850	116.511	121.571	123.105	127.633	131.871	137.127	140.893
94	62.437	69.068	105.303	111.944	117.632	122.715	124.255	128.803	133.059	138.337	142.119
95	63.250	69.925	106.364	113.038	118.752	123.858	125.405	129.973	134.247	139.546	143.344
96	64.063	70.783	107.425	114.131	119.871	125.000	126.554	131.141	135.433	140.755	144.567
97	64.878	71.642	108.486	115.223	120.990	126.141	127.702	132.309	136.619	141.962	145.789
98	65.694	72.501	109.547	116.315	122.108	127.282	128.849	133.476	137.803	143.168	147.010
99	66.510	73.361	110.607	117.407	123.225	128.422	129.996	134.642	138.987	144.373	148.230
100	67.328	74.222	111.667	118.498	124.342	129.561	131.142	135.807	140.169	145.577	149.449

t Table

cum. prob	t ₉₀	t ₇₅	t ₆₀	t ₄₅	t ₃₀	t ₁₅	t ₀₇₅	t ₁₀	t ₀₅	t ₀₂₅	t ₀₁	t ₀₀₅	t ₀₀₁	t ₀₀₀₅
one-tail	0.50	0.25	0.20	0.15	0.10	0.05	0.025	0.01	0.005	0.001	0.0005			
two-tails	1.00	0.50	0.40	0.30	0.20	0.10	0.05	0.02	0.01	0.002	0.001			
df														
1	0.000	1.000	1.376	1.963	3.078	6.314	12.71	31.82	63.66	318.31	636.62			
2	0.000	0.816	1.061	1.386	1.886	2.920	4.303	6.965	9.925	22.327	31.599			
3	0.000	0.765	0.978	1.250	1.638	2.353	3.182	4.541	5.841	10.215	12.924			
4	0.000	0.741	0.941	1.190	1.533	2.132	2.776	3.747	4.604	7.173	8.610			
5	0.000	0.727	0.920	1.156	1.476	2.015	2.571	3.365	4.032	5.893	6.869			
6	0.000	0.718	0.906	1.134	1.440	1.943	2.447	3.143	3.707	5.206	5.959			
7	0.000	0.711	0.896	1.119	1.415	1.895	2.366	2.998	3.499	4.785	5.408			
8	0.000	0.706	0.889	1.108	1.397	1.860	2.306	2.938	3.355	4.501	5.041			
9	0.000	0.703	0.883	1.100	1.383	1.833	2.282	2.821	3.250	4.297	4.781			
10	0.000	0.700	0.879	1.093	1.372	1.812	2.228	2.764	3.169	4.144	4.587			
11	0.000	0.697	0.876	1.088	1.363	1.796	2.201	2.718	3.106	4.025	4.437			
12	0.000	0.695	0.873	1.083	1.356	1.782	2.179	2.681	3.055	3.930	4.318			
13	0.000	0.694	0.870	1.079	1.350	1.771	2.160	2.650	3.012	3.852	4.221			
14	0.000	0.692	0.868	1.076	1.345	1.761	2.145	2.624	2.977	3.787	4.140			
15	0.000	0.691	0.866	1.074	1.341	1.753	2.131	2.602	2.947	3.733	4.073			
16	0.000	0.690	0.865	1.071	1.337	1.746	2.120	2.583	2.921	3.686	4.015			
17	0.000	0.689	0.863	1.069	1.333	1.740	2.110	2.567	2.898	3.646	3.965			
18	0.000	0.688	0.862	1.067	1.330	1.734	2.101	2.552	2.879	3.610	3.922			
19	0.000	0.688	0.861	1.066	1.328	1.729	2.093	2.538	2.861	3.579	3.883			
20	0.000	0.687	0.860	1.064	1.325	1.725	2.086	2.526	2.845	3.552	3.850			
21	0.000	0.686	0.859	1.063	1.323	1.721	2.080	2.518	2.831	3.527	3.819			
22	0.000	0.686	0.858	1.061	1.321	1.717	2.074	2.508	2.819	3.505	3.792			
23	0.000	0.685	0.858	1.060	1.319	1.714	2.069	2.500	2.807	3.485	3.768			
24	0.000	0.685	0.857	1.059	1.318	1.711	2.064	2.492	2.797	3.467	3.745			
25	0.000	0.684	0.856	1.058	1.316	1.708	2.060	2.485	2.787	3.450	3.725			
26	0.000	0.684	0.856	1.058	1.315	1.706	2.056	2.479	2.779	3.435	3.707			
27	0.000	0.684	0.855	1.057	1.314	1.703	2.052	2.473	2.771	3.421	3.690			
28	0.000	0.683	0.855	1.056	1.313	1.701	2.048	2.467	2.763	3.408	3.674			
29	0.000	0.683	0.854	1.055	1.311	1.699	2.045	2.462	2.756	3.396	3.659			
30	0.000	0.683	0.854	1.055	1.310	1.697	2.042	2.457	2.750	3.385	3.646			
40	0.000	0.681	0.851	1.050	1.303	1.684	2.021	2.423	2.704	3.307	3.551			
60	0.000	0.679	0.848	1.045	1.296	1.671	2.000	2.390	2.660	3.232	3.460			
80	0.000	0.678	0.846	1.043	1.292	1.664	1.990	2.374	2.639	3.195	3.416			
100	0.000	0.677	0.845	1.042	1.290	1.660	1.984	2.364	2.626	3.174	3.390			
1000	0.000	0.675	0.842	1.037	1.282	1.646	1.962	2.330	2.581	3.098	3.300			
Z	0.000	0.674	0.842	1.036	1.282	1.645	1.960	2.326	2.576	3.090	3.291			
	0%	50%	60%	70%	80%	90%	95%	98%	99%	99.8%	99.9%			
	Confidence Level													

F Distribution critical values for P=0.10

DF	Denominator													
	Numerator DF													
	1	2	3	4	5	7	10	15	20	30	60	120	500	1000
1	39.864	49.500	53.593	55.833	57.240	58.906	60.195	61.220	61.740	62.265	62.794	63.061	63.264	63.296
2	8.5264	8.9999	9.1618	9.2434	9.2926	9.3491	9.3915	9.4248	9.4413	9.4580	9.4745	9.4829	9.4893	9.4902
3	5.5384	5.4624	5.3907	5.3426	5.3092	5.2661	5.2304	5.2003	5.1845	5.1681	5.1513	5.1425	5.1358	5.1347
4	4.5448	4.3245	4.1909	4.1073	4.0505	3.9790	3.9198	3.8704	3.8443	3.8175	3.7896	3.7753	3.7643	3.7625
5	4.0605	3.7798	3.6194	3.5202	3.4530	3.3679	3.2974	3.2379	3.2067	3.1740	3.1402	3.1228	3.1094	3.1071
7	3.5895	3.2575	3.0740	2.9605	2.8833	2.7850	2.7025	2.6322	2.5947	2.5555	2.5142	2.4927	2.4761	2.4735
10	3.2850	2.9244	2.7277	2.6054	2.5216	2.4139	2.3226	2.2434	2.2007	2.1554	2.1071	2.0818	2.0618	2.0587
15	3.0731	2.6951	2.4898	2.3615	2.2729	2.1582	2.0593	1.9722	1.9243	1.8727	1.8168	1.7867	1.7629	1.7590
20	2.9746	2.5893	2.3801	2.2490	2.1582	2.0397	1.9368	1.8450	1.7939	1.7383	1.6768	1.6432	1.6163	1.6118
30	2.8808	2.4887	2.2761	2.1423	2.0493	1.9269	1.8195	1.7222	1.6674	1.6064	1.5376	1.4990	1.4669	1.4617
60	2.7911	2.3932	2.1774	2.0409	1.9457	1.8194	1.7070	1.6034	1.5435	1.4756	1.3953	1.3476	1.3060	1.2989
120	2.7478	2.3473	2.1300	1.9924	1.8959	1.7675	1.6523	1.5450	1.4821	1.4094	1.3203	1.2646	1.2123	1.2026
500	2.7157	2.3132	2.0947	1.9561	1.8588	1.7288	1.6115	1.5009	1.4354	1.3583	1.2600	1.1937	1.1215	1.1057
1000	2.7106	2.3080	2.0892	1.9505	1.8530	1.7228	1.6051	1.4941	1.4281	1.3501	1.2500	1.1813	1.1031	1.0844

F Distribution critical values for P=0.05

DF	Denominator													
	Numerator DF													
	1	2	3	4	5	7	10	15	20	30	60	120	500	1000
1	161.45	199.50	215.71	224.58	230.16	236.77	241.88	245.95	248.01	250.10	252.20	253.25	254.06	254.19
2	18.513	19.000	19.164	19.247	19.296	19.353	19.396	19.429	19.446	19.462	19.479	19.487	19.494	19.495
3	10.128	9.5522	9.2766	9.1172	9.0135	8.8867	8.7855	8.7028	8.6602	8.6165	8.5720	8.5493	8.5320	8.5292
4	7.7086	6.9443	6.5915	6.3882	6.2560	6.0942	5.9644	5.8579	5.8026	5.7458	5.6877	5.6580	5.6352	5.6317
5	6.6078	5.7862	5.4095	5.1922	5.0504	4.8759	4.7351	4.6187	4.5582	4.4958	4.4314	4.3985	4.3731	4.3691
7	5.5914	4.7375	4.3469	4.1202	3.9715	3.7871	3.6366	3.5108	3.4445	3.3758	3.3043	3.2675	3.2388	3.2344
10	4.9645	4.1028	3.7082	3.4780	3.3259	3.1354	2.9782	2.8450	2.7741	2.6996	2.6210	2.5801	2.5482	2.5430
15	4.5431	3.6823	3.2874	3.0556	2.9013	2.7066	2.5437	2.4035	2.3275	2.2467	2.1601	2.1141	2.0776	2.0718
20	4.3512	3.4928	3.0983	2.8660	2.7109	2.5140	2.3479	2.2032	2.1241	2.0391	1.9463	1.8962	1.8563	1.8498
30	4.1709	3.3159	2.9223	2.6896	2.5336	2.3343	2.1646	2.0149	1.9317	1.8408	1.7396	1.6835	1.6376	1.6300
60	4.0012	3.1505	2.7581	2.5252	2.3683	2.1666	1.9927	1.8365	1.7480	1.6492	1.5343	1.4672	1.4093	1.3994
120	3.9201	3.0718	2.6802	2.4473	2.2898	2.0868	1.9104	1.7505	1.6587	1.5544	1.4289	1.3519	1.2804	1.2674
500	3.8601	3.0137	2.6227	2.3898	2.2320	2.0278	1.8496	1.6864	1.5917	1.4820	1.3455	1.2552	1.1586	1.1378
1000	3.8508	3.0047	2.6137	2.3808	2.2230	2.0187	1.8402	1.6765	1.5811	1.4705	1.3318	1.2385	1.1342	1.1096

F Distribution critical values for P=0.02

DF	Denominator													
	1	2	3	4	5	7	10	15	20	30	60	120	500	1000
1	1012.5	1249.5	1350.5	1405.8	1440.6	1481.8	1513.7	1539.1	1551.9	1564.9	1578.0	1584.6	1589.6	1590.4
2	48.505	49.000	49.166	49.249	49.299	49.356	49.398	49.432	49.448	49.465	49.482	49.490	49.496	49.497
3	20.618	18.858	18.110	17.694	17.429	17.110	16.860	16.657	16.553	16.448	16.340	16.286	16.244	16.238
4	14.040	12.142	11.344	10.899	10.616	10.274	10.003	9.7828	9.6696	9.5540	9.4359	9.3760	9.3300	9.3227
5	11.323	9.4544	8.6702	8.2330	7.9530	7.6137	7.3438	7.1234	7.0094	6.8926	6.7728	6.7119	6.6649	6.6573
7	8.9877	7.2026	6.4539	6.0347	5.7647	5.4354	5.1711	4.9531	4.8392	4.7220	4.6007	4.5384	4.4902	4.4825
10	7.6384	5.9336	5.2182	4.8157	4.5549	4.2347	3.9750	3.7580	3.6437	3.5245	3.3999	3.3354	3.2850	3.2770
15	6.7730	5.1355	4.4475	4.0584	3.8052	3.4917	3.2345	3.0168	2.9003	2.7775	2.6468	2.5780	2.5237	2.5151
20	6.3907	4.7875	4.1134	3.7312	3.4817	3.1713	2.9149	2.6955	2.5771	2.4509	2.3148	2.2421	2.1841	2.1747
30	6.0382	4.4695	3.8093	3.4339	3.1877	2.8803	2.6239	2.4020	2.2805	2.1493	2.0047	1.9255	1.8611	1.8505
60	5.7127	4.1785	3.5319	3.1633	2.9207	2.6157	2.3586	2.1326	2.0067	1.8676	1.7085	1.6169	1.5383	1.5251
120	5.5594	4.0423	3.4026	3.0372	2.7963	2.4923	2.2347	2.0059	1.8769	1.7322	1.5613	1.4577	1.3629	1.3458
500	5.4467	3.9428	3.3083	2.9453	2.7057	2.4024	2.1441	1.9128	1.7809	1.6307	1.4468	1.3273	1.2019	1.1750
1000	5.4293	3.9274	3.2937	2.9311	2.6915	2.3884	2.1300	1.8983	1.7659	1.6146	1.4284	1.3053	1.1701	1.1388

F Distribution critical values for P=0.01

DF	Denominator													
	1	2	3	4	5	7	10	15	20	30	60	120	500	1000
1	4052.2	4999.5	5403.4	5624.6	5763.6	5928.4	6055.8	6157.3	6208.7	6260.6	6313.0	6339.4	6359.5	6362.7
2	98.503	99.000	99.166	99.249	99.299	99.356	99.399	99.433	99.449	99.466	99.482	99.491	99.497	99.498
3	34.116	30.817	29.457	28.710	28.237	27.672	27.229	26.872	26.690	26.504	26.316	26.221	26.148	26.137
4	21.198	18.000	16.694	15.977	15.522	14.976	14.546	14.198	14.020	13.838	13.652	13.558	13.486	13.474
5	16.258	13.274	12.060	11.392	10.967	10.455	10.051	9.7222	9.5526	9.3793	9.2020	9.1118	9.0424	9.0314
7	12.246	9.5467	8.4513	7.8466	7.4605	6.9929	6.6201	6.3143	6.1554	5.9920	5.8236	5.7373	5.6707	5.6601
10	10.044	7.5594	6.5523	5.9944	5.6363	5.2001	4.8492	4.5582	4.4055	4.2469	4.0818	3.9964	3.9303	3.9195
15	8.6831	6.3588	5.4169	4.8932	4.5557	4.1416	3.8049	3.5223	3.3719	3.2141	3.0471	2.9594	2.8906	2.8796
20	8.0960	5.8489	4.9382	4.4306	4.1027	3.6987	3.3682	3.0880	2.9377	2.7785	2.6078	2.5167	2.4446	2.4330
30	7.5624	5.3903	4.5098	4.0179	3.6990	3.3046	2.9791	2.7002	2.5486	2.3859	2.2078	2.1108	2.0321	2.0192
60	7.0771	4.9774	4.1259	3.6491	3.3388	2.9530	2.6318	2.3522	2.1978	2.0284	1.8362	1.7264	1.6328	1.6169
120	6.8509	4.7865	3.9490	3.4795	3.1736	2.7918	2.4720	2.1914	2.0345	1.8600	1.6557	1.5330	1.4215	1.4015
500	6.6858	4.6479	3.8210	3.3569	3.0539	2.6751	2.3564	2.0746	1.9152	1.7353	1.5175	1.3774	1.2317	1.2007
1000	6.6603	4.6264	3.8012	3.3379	3.0356	2.6571	2.3387	2.0564	1.8967	1.7158	1.4953	1.3513	1.1947	1.1586

MANIPAL UNIVERSITY

M. PHARM. PART-I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: REGULATORY AFFAIRS (PQA 603)
(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Friday, May 30, 2014

Time: 10:00 – 13:00 Hrs.

Max. Marks: 100

Answer ALL questions.

- 1A. Explain the prequalification application requirements for finished pharmaceutical products for WHO.
- 1B. Explain the data elements of the following as per *USFDA guidelines on animal models*. Characteristics of “Chemical, Biological, Radioactive and Nuclear agents. Natural history of the disease.
- (10+10 = 20 marks)
- 2A. What is a Common Technical Document? Explain its content and format.
- 2B. Explain the tools used for process analytical technology. (PAT).
- (10+10 = 20 marks)
- 3A. Explain the decision tree for identification and qualification of impurities in new drug substances.
- 3B. Explain the different methods to document bioavailability and bioequivalence studies for orally administered drugs.
- (10+10 = 20 marks)
- 4A. Explain the various approaches to perform dissolution profile comparison of an immediate release formulation.
- 4B. What is a combination product and its regulation? Enlist GMP requirements for combination products.
- (10+10 = 20 marks)
- 5A. Enlist various treaties governing IPR and discuss any two in detail.
- 5B. Define Patents. Distinguish between Patents, Copyrights and Trademarks.
- 5C. Write a note on continual improvement of pharmaceutical quality system as per ICH Q10.
- (10+5+5 = 20 marks)



MANIPAL UNIVERSITY

M. PHARM. PART-I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: PHARMACEUTICAL ANALYSIS & PRODUCT DEVELOPMENT (PQA 604)
(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Monday, June 02, 2014

Time: 10:00 – 13:00 Hrs.

Max. Marks: 100

Answer ALL the questions.

- 1A. What is metabolic characterization of drug substance? Explain its applications in drug discovery process.
- 1B. What do you mean by the term “Fingerprinting”? Explain with suitable examples.
- 1C. Write a short note on stability indicating assay methods. Comment on various validation parameters of stability indicating assay.
- (5+5+10 = 20 marks)
- 2A. Explain the principle and reactions involved in the limit test for heavy metals. How 20 ppm lead standard solution is prepared?
- 2B. Explain the principle and procedure for the determination of water by residual titration method.
- 2C. Name the various ion selective electrodes. Explain the construction and working of a liquid membrane electrode. Write a note on liquid junction potentials.
- (5+5+10 = 20 marks)
- 3A. Write in detail various stages of “herbal standardization” using suitable examples. Explain its various applications.
- 3B. Explain short term and long term stability studies. How the shelf life of the formulation is decided?
- (10+10 = 20 marks)
- 4A. How test for uniformity of weight of a single dose preparation is performed? Discuss its acceptance criteria.
- 4B. Discuss the various tests for evaluating the plastic containers for non-injectable preparations and write the acceptance limits.
- 4C. Discuss the important guidelines to be followed while developing a method for dissolution testing for modified release dosage forms.
- 4D. Discuss the importance of IVIVC in formulation development.
- (5+5+5+5 = 20 marks)
- 5A. Explain the importance of degradation kinetics in stability testing of drug molecules. What is pseudo first order kinetics?
- 5B. What do you mean by term “spiking”? Explain various applications of determination of drug in biological fluids.
- 5C. Describe bacterial endotoxin test for injectable preparations.
- (5+5+10 = 20 marks)

