

BAB 5

SIMPULAN

5.1. Simpulan

Konsentrasi *crospovidone* berpengaruh secara signifikan terhadap sifat fisik tablet dimana konsentrasi *crospovidone* dapat meningkatkan kerapuhan, menurunkan waktu hancur tablet, menurunkan waktu pembasahan tablet, dan meningkatkan rasio absorpsi air. Konsentrasi PVP K-30 juga berpengaruh secara signifikan terhadap sifat fisik tablet dimana konsentrasi PVP K-30 dapat meningkatkan kekerasan tablet, menurunkan kerapuhan, meningkatkan waktu hancur tablet, serta meningkatkan waktu pembasahan tablet. Interaksi konsentrasi *crospovidone* dan konsentrasi PVP K-30 juga berpengaruh secara signifikan terhadap sifat fisik tablet, interaksi ini memberikan pengaruh secara signifikan dalam menurunkan kekerasan tablet serta meningkatkan kerapuhan tablet.

Formula optimum ODT domperidone dapat diperoleh dengan kombinasi konsentrasi *crospovidone* 6,75% dan konsentrasi PVP K-30 0,6125%, dengan hasil teoritis, kekerasan tablet 2,53 Kp, kerapuhan tablet 0,98%, waktu hancur tablet 19,41 detik, waktu pembasahan 23,65 detik, rasio absorpsi air 46,48%, dan persen efisiensi disolusi 93,25%

5.2. Alur Penelitian Selanjutnya

Sebaiknya perlu dilakukan uji stabilitas dengan waktu pengamatan yang lebih panjang, yaitu tidak kurang dari 3 bulan serta dilakukan penelitian pembuktian beberapa formula optimum terpilih, yang kemudian dibandingkan dengan hasil secara teoritis.

DAFTAR PUSTAKA

- Albright, L.V., 2004, Domperidone in Lactation : Use as a Galactogogue, **International Journal of Pharmaceutical Compounding**, 8(5), 329-335.
- Anonim, 1979, **Farmakope Indonesia**, ed. III, Departemen Kesehatan RI, Jakarta, 6-8.
- Anonim, 1995, **Farmakope Indonesia**, ed. IV, Departemen Kesehatan RI, Jakarta, 4, 166, 449-450, 488-489, 515, 683, 783-784, 999-1000.
- Anonim, 2005, **European pharmacopeia**, 5th ed., EDQM, English, 1473-1475.
- Anonim, 2006, USP29-NF24, General Information Chapter ‘<1174> Powder Flow’, **US Pharmacopeial Convention**, Rockville, MD, USA.
- Ansel, C.H., 1989, **Pengantar Bentuk Sediaan Farmasi**, ed. 4, Penerbit Universitas Indonesia, Jakarta, 244-245, 259-272.
- Banakar, U.V., 1992, **Pharmaceutical Disolution Testing**, Marcel Dekker Inc., New York, 19-25.
- Banker, G.S. and N.R. Anderson, 1986, Tablet, in: **The Theory and Practice of Industrial Pharmacy: Tablet**, L. Lachman, H.A. Lieberman, and J.L. Kanig (Eds.), 3rd ed., Lea and Febiger, Philadelphia, 259, 295, 299, 316-329.
- Bhowmik, D., B. Chiranjib, Krishnakanth, Pankaj, and R. Chandira, 2009, Fast Dissolving Tablet: An Overview, **Journal of Chemical and Pharmaceutical Research**, 1(1), 163-177.
- Bolton, S., 1990, **Pharmaceutical Statistic: Practical and Clinical Application**, 2nd ed., Marcel Dekker, Inc., New York, 324-427
- Chawla, M. and G.Srinivasan, 2011, Evaluation of Galen IQ Polymer in Tramadol Hydrochloride Orally Disintegrating Tablet. **International Journal of Drug Delivery**, 3, 439-455.

Deshmukh, V. N., 2012, Mouth Dissolving Drug Delivery System: A Review, **Int. J. Pharm. Tech. Res.**, 4(1), 412-421.

Dibbern, H.W., R.M. Muller, and E. Wirbitzki, 2002, **UV and IR Spectra**, Editio Cantor Verlag, 579.

Dobetti L., 2003, Fast Disintegrating Tablets, **US Patent** 6, 596, 311.

Duchene, D., 1983, Tablet Disintegration, In: **Topic in Pharmaceutical Science**, P.D. Breimer, and P. Spesier (Eds.), Proceeding of The 43rd International Congress of Pharmaceutical, Amsterdam-New York-Oxford, 387-399.

Fierse, E. F. and A. T. Hagen, 1986, Pre formulation, In: **The Theory and Practice of Industrial Pharmacy**, L. Lachman, H. A. Lieberman, and J. L. Kanig (Eds.), 3rd ed., Lea and Febiger, Philadelphia, 183-184.

Fu, Y., S. Yang, S.H. Jeong, S. Kimura, and K. Park, 2004, Orally Fast Disintegrating Tablets: Developments, Technologies, Taste-Masking and Clinical Studies, **Critical Reviews in Therapeutic Drug Carrier Systems**, 21(6), 433-475.

Fudholi, A., 1985, Metodologi Formulasi dalam Kompresi Direk, **Medika**, 9, 586-593.

Ghost, T.K., D.J. Chatterjee, W.R. Pfister, V.R. Jarugula, E.O. Fadiran, J.P. Hunt, L.J. Lesko, V.K. Tammara, and D.B. Hare, 2005, Quick Dissolving Oral Dosage Forms: Scientific and Regulatory Considerations from A Clinical Pharmacology and Biopharmaceutics Perspective. In: T.K. Ghosh dan W.R. Pfister (eds), **Drug Delivery to The Oral Cavity: Molecules to Market**, Boca Raton: Taylor & Francis Group, 344.

Giri, T. K., D. K. Tripathi, and R. Majumdar, 2010, Formulation Aspects In The Development of Orodispersible Tablets: An Overview, **International Journal of Pharmacy and Pharmaceutical Sciences**, 2(3), 38-42.

Goel, H., N. Vora, and V. Rana, 2008, A Novel Approach to Optimize and Formulate Fast Disintegrating Tablets for Nausea and Vomiting, **AAPS Pharm. Sci. Tech.**, 9(3), 774-781.

Green, J.M., 1996, A Practical Guide to Analytical Method Validition, **Analytical Chemistry**, 68, 305-309.

Gulati, A., C.A. Kumar, S.U. Kumar, G.R. Dayal, S. Mansi, and S. Prateek, 2012, Fast Disintegrating Tablets: A never-ending trend, **Novel Science International Journal of Pharmaceutical Science**, 1(5), 245-253.

Guleria, R., N.S. Kaith, and R. Singh, 2011, Improved Dissolution of Domperidone In Solid Dispersion with Polymeric Hydrophilic Additive, **J. Chem. Pharm. Res.**, 3(6), 655-664.

Hsu, A.F. and C-H Han, 2005, Oral Disintegrating Dosage Form, **US Patent Application Publication Number 20050147670A1**.

Khan, K.A., 1975, The Concept of Dissolution Efficiency. **J. Pharm.**, 27(1), 48-49.

Kumar, M.V., P. Sethi, R. Kheri, G.K. Saraogi, and A.K. Singhai, 2011, Orally Disintegrating Tablets: A Review, **International Research Journal of Pharmacy**, 2(4), 16-22.

Kundu, S. and P.K. Sahoo, 2008, Recent Trends in The Developments of Orally Disintegrating Tablet Technology. **Pharma Times**, 40(4), 11-21.

Lachman, L., H.A. Leiberman, and J.L. Kanig, 1986, **The Theory and Practice of Industrial Pharmacy**. 3rd ed., Lea and Febiger, Philadelphia, 564-588.

Langenbucher, F., 1972, Linearization of Dissolution Rate Curve by Weibull Distribution, **Journal of Pharmaceutical Sciences**, 24, 979-981.

Lucas, T. I., R. H. Bishara, and R. H. Seevers, 2004, A Stability Program for the Distribution of Drug Products, **Pharmaceutical Technology**, 7, 68-73.

Martin, A., J. Swarbrick, dan A. Cammarata, 1993, **Farmasi Fisik: Dasar-dasar Kimia Fisika dalam Ilmu Farmasetik**, vol. 2, ed. 3, terjemahan Yoshita, Universitas Indonesia, Jakarta, 1135.

Panigrahi, R. and S. Behera, 2010, **A Review on Fast Dissolving Tablets**, Webmed Central, 1(9), 2-15.

Parrott, E.L., 1971, **Pharmaceutical Technology Fundamental Pharmaceutics**, 3rd ed., Burgess Publishing Company, Minneapolis, 17-19, 82, 160-162.

Rangole, U.S., P.S. Kawtikwar, and D.M. Sakarkar, 2008, Formulation and In-vitro Evaluation of Rapidly Disintegrating Tablets Using Hydrochlorothiazide as a Model Drug, **Research J. Pharm. and Tech.**, 1(4), 349-352.

Rowe, R. C., P. J. Sheskey, and M. E. Quiinn, 2009, **Handbook of Pharmaceutical Excipients**, 6th ed., The Pharmaceutical Press, London, 118-119, 376-377, 404, 424-425, 728.

Seager, H., 1998, Drug-Delivery Products and The Zydis Fast-Dissolving Dosage. **J. Pharm. Pharmacol.**, 50(4), 375-82.

Shargel, L. and A.B.C. Yu, 1999, **Applied Biopharmaceutics and Pharmacokinetics**, 4th ed McGraw-Hill. New York, 8, 132, 169-200.

Sharma, S. and P. K. Suresh, 2010, Formulation, In Vitro Characterization and Stability Studies of Self Microemulsifying Drug Delivery Systems of Domperidone, **International Journal of Innovative Pharmaceutical Research**, 1(4), 66-73.

Shervington, L.A. and A. Shervington, 1998, Guaifenesin, In: **Analytical Profiles of Drug Substances and Exipients**, H.G. Brittain (Ed.), vol. 25, Academic Press, London, 152.

Shihora, H. and S. Panda, 2011, Superdisintegrants, Utility in Dosage Forms: A Quick Review, **Journal of Pharmaceutical Science and Bioscientific Research**, 1(3), 148-153.

Shukla, D., S. Chakraborty, S. Singh, and B. Mishra, 2009, Mouth Dissolving Tablets I: An Overview of Formulation Technology, **Scientia Pharmaceutica**, 76, 309-326.

Siregar, C. J. P., 1992, **Proses Validasi Manufaktur Sediaan Tablet**, Institut Teknologi Bandung, Bandung, 29-31.

Sulaiman, T.N.S., 2007, **Teknologi dan Formulasi Sediaan Tablet**, Cetakan Pertama. Yogyakarta: Mitra Communications Indonesia, 149-153.

Sutradhar, K.B., D.T.Akhter, and R.Uddin, 2012, Formulation and Evaluation of Taste Masked Oral Dispersible Tablets of Domperidone Using Sublimation Method, **Int. J. Pharm. Sci.**, 4(2), 727-732.

Sweetman, S. C., 2009, **Martindale: The Complete Drug Reference**, 36th ed., Pharmaceutical Pres., London, 1726.

Thatipamula R.P., C.R. Palem, R. Gannu, S. Mudragada, and M.R.Yamsani, 2011, Formulation and In Vitro Characterization of Domperidone Loaded Solid Lipid Nanoparticles and Nanostructured Lipid Carriers, **Daru**, 19(1), 23-32.

Velmurugan, S. and S. Vinushita, 2010, Oral Disintegrating Tablets: An Overview, **International Journal of Chemical and Pharmaceutical Sciences**, 1(2), 1-12.

Wagner, J.G., 1971, **Biopharmaceutics and Relevant Pharmacokinetics**, 1st ed., Drug Intelligence Publications, Illinois, 64-110.

Widiawati, L., 1998, **Pengaruh Konsentrasi PVP K-30 Sebagai Bahan Pengikat Terhadap Sifat Fisik Tablet Parasetamol**, skripsi, Universitas Katolik Widya Mandala Surabaya.

Zainuddin, M., 2000, **Validasi Metode Analisis Kuantitatif Secara Spektrofotometris Ultra Ungu-Sinar Tampak (UV-Vis)**, Universitas Airlangga, Surabaya.

LAMPIRAN A
HASIL UJI MUTU FISIK GRANUL

Mutu fisik yang diuji	Rep.	Uji	Formula ODT Domperidone				Persyaratan
			F1	F2	F3	F4	
Kelembaban serbuk (%)	I	-	3,01	3,87	2,8	3,01	2-5% (Ansel, 1989)
	II	-	3,42	3,12	2,96	3,55	
	III	-	3,14	3,68	2,57	3,16	
	\bar{x}		3,19	3,56	2,78	3,24	
	SD		0,21	0,39	0,20	0,28	
Densitas (g/mL)	I	ρ bulk	0,46	0,47	0,49	0,43	-
		ρ tapped	0,55	0,58	0,57	0,53	
	II	ρ bulk	0,47	0,43	0,47	0,39	
		ρ tapped	0,55	0,52	0,55	0,47	
	III	ρ bulk	0,45	0,41	0,48	0,42	
		ρ tapped	0,53	0,50	0,56	0,51	
	\bar{x}	ρ bulk	0,46	0,44	0,48	0,41	
	SD	ρ bulk	0,01	0,03	0,01	0,02	
<i>Hausner Ratio</i>	X \square	ρ tapped	0,54	0,53	0,56	0,50	$\leq 1,25$ (Anonim, 2006)
	SD	ρ tapped	0,01	0,04	0,01	0,03	
	I	-	1,18	1,23	1,16	1,23	
	II	-	1,16	1,22	1,18	1,19	
	III	-	1,19	1,22	1,18	1,22	
<i>Carr's Index (%)</i>	\bar{x}		1,18	1,22	1,17	1,21	≤ 20 (Anonim, 2006)
	SD		0,01	0,01	0,01	0,02	
	I	-	15,0	19,0	14,0	19,0	
	II	-	14,0	18,0	15,5	16,0	
	III	-	16,0	18,0	15,0	18,0	
\bar{x}			15,00	18,33	14,83	17,67	
	SD		1,00	0,58	0,76	1,53	

LAMPIRAN B
HASIL UJI KERAGAMAN BOBOT ODT DOMPERIDONE

Hasil Uji Keragaman Bobot Tablet Formula 1

No.	Replikasi I		Replikasi II		Replikasi III	
	Bobot Tablet (mg)	Y (%)	Bobot Tablet (mg)	Y (%)	Bobot Tablet (mg)	Y (%)
1	103,3	102,03	105,6	101,84	101,5	103,30
2	104,1	102,82	104,2	100,49	102,0	103,80
3	106,2	104,90	102,0	98,37	102,7	104,52
4	109,5	108,16	102,9	99,23	101,2	102,99
5	106,6	105,29	105,7	101,93	103,2	105,03
6	104,9	103,61	104,3	100,58	101,5	103,30
7	105,6	104,31	105,1	101,36	100,3	102,07
8	106,4	105,10	106,5	102,71	102,0	103,80
9	107,1	105,79	103,8	100,10	102,4	104,21
10	106,8	105,49	106,5	102,71	104,2	106,04
\bar{x}	106,05	104,75	104,7	100,93	102,1	103,91
PK (%)	104,75		100,93		103,91	
SD	1,71		1,44		1,12	
KV	1,63		1,43		1,08	

Keterangan : PK = Penetapan Kadar
 SD = Standart Deviasi
 KV = Koefisien Variasi

Hasil Uji Keragaman Bobot Tablet Formula 2

No.	Replikasi I		Replikasi II		Replikasi III	
	Bobot Tablet (mg)	Y (%)	Bobot Tablet (mg)	Y (%)	Bobot Tablet (mg)	Y (%)
1	101,6	100,59	97,5	98,06	99,6	99,75
2	98,3	97,33	100,4	100,98	101,3	101,45
3	102,0	100,99	99,9	100,48	100,2	100,35
4	102,3	101,29	102,1	102,69	98,4	98,54
5	101,5	100,49	97,7	98,26	100,8	100,95
6	103,8	102,77	97,1	97,66	96,2	96,34
7	100,5	99,50	99,12	99,69	98,2	98,34
8	104,6	103,56	97,5	98,06	97,7	97,84
9	100,2	99,21	99,1	99,67	97,7	97,84
10	103,7	102,67	98,4	98,97	102,0	102,15
\bar{x}	101,85	100,84	98,9	99,45	99,21	99,36
PK (%)	100,84		99,47		99,36	
SD		1,88		1,59		1,86
KV		1,86		1,60		1,87

Hasil Uji Keragaman Bobot Tablet Formula 3

No.	Replikasi I		Replikasi II		Replikasi III	
	Bobot Tablet (mg)	Y (%)	Bobot Tablet (mg)	Y (%)	Bobot Tablet (mg)	Y (%)
1	102,3	101,60	101,7	101,16	103,0	98,55
2	101,8	101,10	98,5	97,98	103,7	97,31
3	99,4	98,72	103,2	102,65	100,2	98,08
4	97,7	97,03	102,7	102,15	102,5	97,12
5	98,0	97,33	99,3	98,77	101,9	97,50
6	98,7	98,03	104,8	104,24	102,0	97,60
7	100,2	99,52	102,2	101,66	101,7	99,22
8	98,2	97,53	102,4	101,85	102,5	95,88
9	103,0	102,30	100,6	100,06	101,5	98,08
10	102,5	101,80	101,5	100,96	100,8	96,45
\bar{x}	100,18	99,50	101,69	101,15	101,98	97,58
PK (%)	99,50		101,15		97,58	
SD		2,04		1,84		0,98
KV		2,05		1,82		1,00

Hasil Uji Keragaman Bobot Tablet Formula 4

No.	Replikasi I		Replikasi II		Replikasi III	
	Bobot Tablet (mg)	Y (%)	Bobot Tablet (mg)	Y (%)	Bobot Tablet (mg)	Y (%)
1	104,4	100,02	104,3	101,23	104,8	101,98
2	102,2	97,91	106,4	103,27	104,3	101,49
3	104,5	100,12	101,1	98,13	101,8	99,06
4	101,2	96,95	100,2	97,25	100,5	97,80
5	101,9	97,63	110,0	106,76	105,7	102,86
6	100,6	96,38	101,4	98,42	104,2	101,40
7	101,3	97,05	105,2	102,10	100,7	97,99
8	102,3	98,01	100,1	97,15	103,4	100,62
9	102,7	98,39	103,4	100,36	106,3	103,44
10	102,6	98,30	107,5	104,34	103,8	101,01
\bar{x}	102,37	98,08	103,96	100,90	103,55	100,76
PK (%)	98,08		100,90		100,76	
SD	1,23		3,25		1,93	
KV	1,25		3,22		1,91	

LAMPIRAN C

HASIL UJI KESERAGAMAN KANDUNGAN ODT DOMPERIDONE

Hasil Uji Keseragaman Kandungan Tablet Formula 1

Replikasi	Abs.	Bobot Tablet (mg)	Bobot Sampel (mg)	Kons. Sampel ($\mu\text{g}/\text{ml}$)	Kons. Teoritis ($\mu\text{g}/\text{ml}$)	Kadar (%)
I	0,254	103,3	95,2	7,89	7,37	107,07
	0,249	105,6	99,1	7,72	7,51	102,79
	0,251	106,4	101,6	7,79	7,64	101,95
	0,253	107,1	101,4	7,86	7,57	103,76
	0,264	106,8	102,2	8,25	7,66	107,73
	0,263	104,1	99,6	8,21	7,65	107,29
	0,253	106,2	101,3	7,86	7,63	102,98
	0,256	109,5	100,2	7,96	7,32	108,80
	0,259	106,6	100,7	8,07	7,56	106,79
	0,265	104,9	99,8	8,28	7,61	108,82
\bar{x}						105,80
SD						2,64
KV						2,49
II	0,252	105,1	100,8	7,82	7,67	101,96
	0,235	106,5	96,3	7,22	7,23	99,85
	0,247	103,8	97,6	7,65	7,52	101,65
	0,236	106,5	99,4	7,26	7,47	97,20
	0,248	105,6	98,5	7,68	7,46	102,95
	0,240	104,2	97,1	7,40	7,45	99,25
	0,249	102,0	96,3	7,72	7,55	102,18
	0,252	102,9	99,4	7,82	7,73	101,23
	0,241	105,7	99,8	7,43	7,55	98,43
	0,247	104,3	99,6	7,65	7,64	100,09
\bar{x}						100,48
SD						1,83
KV						1,82

Replikasi	Abs.	Bobot Tablet (mg)	Bobot Sampel (mg)	Kons. Sampel ($\mu\text{g}/\text{ml}$)	Kons. Teoritis ($\mu\text{g}/\text{ml}$)	Kadar (%)
III	0,249	101,2	96,3	7,72	7,61	101,37
	0,245	103,2	98,1	7,58	7,60	99,62
	0,240	101,5	97,4	7,40	7,68	96,38
	0,254	100,3	95,4	7,89	7,61	103,74
	0,251	102,0	98,5	7,79	7,73	100,81
	0,242	102,4	97,1	7,47	7,59	98,47
	0,252	104,2	99,7	7,82	7,65	102,21
	0,242	101,5	95,4	7,47	7,52	99,35
	0,241	102,0	96,6	7,43	7,58	98,13
	0,255	102,7	99,5	7,93	7,75	102,30
				\bar{x}	100,24	
				SD	2,25	
				KV	2,25	

Hasil Uji Keseragaman Kandungan Tablet Formula 2

Replikasi	Abs.	Bobot Tablet (mg)	Bobot Sampel (mg)	Kons. Sampel ($\mu\text{g}/\text{ml}$)	Kons. Teoritis ($\mu\text{g}/\text{ml}$)	Kadar (%)
I	0,249	102,3	96,9	7,72	7,58	101,84
	0,247	101,5	96,4	7,65	7,60	100,64
	0,256	100,2	98,3	7,96	7,85	101,48
	0,246	103,7	98,1	7,61	7,57	100,57
	0,241	101,6	96,8	7,43	7,62	97,54
	0,246	98,3	93,2	7,61	7,58	100,35
	0,254	102,0	97,9	7,89	7,68	102,81
	0,243	104,6	98,5	7,51	7,53	99,63
	0,246	103,8	97,6	7,61	7,52	101,19
	0,245	100,5	94,8	7,58	7,55	100,39
				\bar{x}	100,64	
				SD	1,41	
				KV	1,40	

Replikasi	Abs.	Bobot Tablet (mg)	Bobot Sampel (mg)	Kons. Sampel (µg/ml)	Kons. Teoritis (µg/ml)	Kadar (%)
II	0,246	97,5	92,4	7,61	7,58	100,39
	0,247	99,1	94,8	7,65	7,65	99,92
	0,238	98,4	92,5	7,33	7,52	97,45
	0,248	98,9	93,8	7,68	7,59	101,25
	0,249	102,1	96,7	7,72	7,58	101,85
	0,246	97,5	96,1	7,61	7,89	96,53
	0,248	100,4	97,8	7,68	7,79	98,58
	0,247	99,9	94,7	7,65	7,58	100,83
	0,236	97,7	91,3	7,26	7,48	97,08
	0,238	97,1	92,7	7,33	7,64	95,96
						\bar{x} 98,98
						SD 2,13
						KV 2,15
III	0,247	100,8	94,9	7,65	7,53	101,53
	0,243	97,7	90,8	7,51	7,44	100,95
	0,244	100,2	95,1	7,54	7,59	99,31
	0,241	98,4	93,3	7,43	7,59	98,01
	0,245	99,6	94,8	7,58	7,61	99,49
	0,242	101,3	95,7	7,47	7,56	98,84
	0,252	102,0	97,7	7,82	7,66	102,10
	0,234	97,7	88,4	7,19	7,24	99,29
	0,239	96,2	91,8	7,36	7,63	96,46
	0,234	98,2	90,2	7,19	7,35	97,81
						\bar{x} 99,38
						SD 1,75
						KV 1,76

Hasil Uji Keseragaman Kandungan Tablet Formula 3

Replikasi	Abs.	Bobot Tablet (mg)	Bobot Sampel (mg)	Kons. Sampel ($\mu\text{g}/\text{ml}$)	Kons. Teoritis ($\mu\text{g}/\text{ml}$)	Kadar (%)
I	0,242	102,3	97,7	7,47	7,64	97,77
	0,237	98,7	93,2	7,29	7,55	96,55
	0,252	103,0	98,4	7,82	7,64	102,36
	0,243	102,5	96,1	7,51	7,50	100,06
	0,247	98,0	94,8	7,65	7,74	98,81
	0,244	101,8	95,7	7,54	7,52	100,27
	0,244	99,4	92,3	7,54	7,43	101,51
	0,232	97,7	92,9	7,12	7,61	93,55
	0,249	100,2	94,8	7,72	7,57	101,96
	0,246	98,2	93,7	7,61	7,63	99,71
					\bar{x}	99,26
					SD	2,71
					KV	2,73
II	0,247	104,8	99,5	7,65	7,60	100,67
	0,249	102,2	97,7	7,72	7,65	100,91
	0,256	102,4	98,4	7,96	7,69	103,61
	0,238	102,7	96,1	7,33	7,49	97,90
	0,252	99,3	94,6	7,82	7,62	102,65
	0,248	101,7	96,8	7,68	7,61	100,89
	0,245	98,5	92,5	7,58	7,51	100,84
	0,248	103,2	96,9	7,68	7,51	102,27
	0,252	100,6	94,5	7,82	7,51	104,10
	0,247	101,5	96,2	7,65	7,58	100,85
					\bar{x}	101,47
					SD	1,77
					KV	1,75

Replikasi	Abs.	Bobot Tablet (mg)	Bobot Sampel (mg)	Kons. Sampel ($\mu\text{g}/\text{ml}$)	Kons. Teoritis ($\mu\text{g}/\text{ml}$)	Kadar (%)
III	0,233	103,0	97,3	7,15	7,56	94,64
	0,246	101,7	96,2	7,61	7,57	100,58
	0,239	102,5	98,4	7,36	7,68	95,88
	0,243	101,5	96,1	7,51	7,57	99,09
	0,241	101,9	96,1	7,43	7,54	98,54
	0,239	102,0	97,9	7,36	7,68	95,90
	0,235	103,7	97,5	7,22	7,52	96,02
	0,244	100,2	95,6	7,54	7,63	98,79
	0,241	102,5	96,3	7,43	7,52	98,92
	0,241	100,8	95,8	7,43	7,60	97,78
						\bar{x}
						SD
						KV

Hasil Uji Keseragaman Kandungan Tablet Formula 4

Replikasi	Abs.	Bobot Tablet (mg)	Bobot Sampel (mg)	Kons. Sampel ($\mu\text{g}/\text{ml}$)	Kons. Teoritis ($\mu\text{g}/\text{ml}$)	Kadar (%)
I	0,236	101,9	96,8	7,26	7,60	95,50
	0,226	100,6	95,3	6,90	7,58	91,11
	0,239	102,7	98,2	7,36	7,65	96,27
	0,246	102,6	97,8	7,61	7,63	99,81
	0,235	104,4	98,7	7,22	7,56	95,50
	0,242	102,2	97,5	7,47	7,63	97,88
	0,238	101,3	96,2	7,33	7,60	96,46
	0,244	102,3	97,1	7,54	7,59	99,31
	0,232	104,5	99,1	7,12	7,59	93,80
	0,236	101,2	94,7	7,26	7,49	96,95
						\bar{x}
						SD
						KV

Replikasi	Abs.	Bobot Tablet (mg)	Bobot Sampel (mg)	Kons. Sampel ($\mu\text{g}/\text{ml}$)	Kons. Teoritis ($\mu\text{g}/\text{ml}$)	Kadar (%)
II	0,241	110,0	103,1	7,43	7,50	99,15
	0,249	101,4	96,3	7,72	7,60	101,58
	0,243	105,2	100,4	7,51	7,63	98,30
	0,244	100,1	96,3	7,54	7,70	97,98
	0,252	104,3	99,2	7,82	7,61	102,82
	0,249	106,4	101,9	7,72	7,66	100,73
	0,252	101,1	96,6	7,82	7,64	102,35
	0,247	100,2	97,1	7,65	7,75	98,63
	0,250	103,4	98,1	7,75	7,59	102,14
	0,248	107,5	102,8	7,68	7,65	100,41
					\bar{x}	100,41
					SD	1,80
					KV	1,79
III	0,249	100,5	94,3	7,72	7,51	102,81
	0,252	103,8	98,5	7,82	7,59	103,05
	0,252	104,3	99,2	7,82	7,61	102,82
	0,243	106,3	101,1	7,51	7,61	98,64
	0,255	105,7	100,3	7,93	7,59	104,45
	0,251	104,2	98,2	7,79	7,54	103,30
	0,252	104,8	97,4	7,82	7,44	105,22
	0,240	100,7	94,8	7,40	7,53	98,25
	0,254	103,4	98,3	7,89	7,61	103,79
	0,251	101,8	96,5	7,79	7,58	102,70
					\bar{x}	102,50
					SD	2,29
					KV	2,23

LAMPIRAN D
HASIL UJI KESERAGAMAN UKURAN ODT DOMPERIDONE

Hasil Uji Keseragaman Ukuran Formula 1

No	Replikasi I		Replikasi II		Replikasi III	
	Diameter (cm)	Tebal (cm)	Diameter (cm)	Tebal (cm)	Diameter (cm)	Tebal (cm)
1	0,610	0,370	0,610	0,360	0,610	0,360
2	0,610	0,370	0,610	0,360	0,605	0,345
3	0,610	0,380	0,605	0,350	0,615	0,340
4	0,610	0,370	0,610	0,360	0,605	0,350
5	0,610	0,365	0,610	0,370	0,615	0,360
6	0,610	0,380	0,615	0,370	0,610	0,355
7	0,605	0,380	0,605	0,375	0,610	0,355
8	0,605	0,350	0,615	0,350	0,605	0,355
9	0,610	0,370	0,610	0,365	0,605	0,360
10	0,610	0,370	0,605	0,370	0,605	0,360
11	0,610	0,370	0,605	0,360	0,610	0,350
12	0,610	0,370	0,610	0,360	0,615	0,365
13	0,615	0,370	0,605	0,350	0,615	0,355
14	0,610	0,360	0,610	0,370	0,615	0,350
15	0,610	0,385	0,605	0,360	0,610	0,370
16	0,610	0,365	0,610	0,375	0,615	0,365
17	0,615	0,360	0,610	0,370	0,610	0,350
18	0,610	0,360	0,610	0,360	0,615	0,350
19	0,610	0,370	0,605	0,375	0,605	0,360
20	0,610	0,350	0,610	0,350	0,610	0,350
\bar{X}	0,61	0,3683	0,6088	0,363	0,6103	0,3553
SD	0,0023	0,0092	0,0032	0,0087	0,0041	0,0073
KV	0,37609	2,5026	0,5246	2,3816	0,6764	2,0663

Hasil Uji Keseragaman Ukuran Formula 2

No	Replikasi I		Replikasi II		Replikasi III	
	Diameter (cm)	Tebal (cm)	Diameter (cm)	Tebal (cm)	Diameter (cm)	Tebal (cm)
1	0,610	0,350	0,605	0,350	0,610	0,350
2	0,615	0,360	0,605	0,345	0,610	0,345
3	0,605	0,364	0,605	0,350	0,605	0,360
4	0,615	0,370	0,615	0,350	0,615	0,350
5	0,605	0,360	0,605	0,360	0,605	0,345
6	0,610	0,360	0,605	0,350	0,605	0,350
7	0,610	0,355	0,605	0,345	0,605	0,340
8	0,605	0,360	0,605	0,350	0,605	0,360
9	0,605	0,365	0,610	0,350	0,605	0,340
10	0,615	0,360	0,605	0,350	0,610	0,350
11	0,605	0,355	0,610	0,340	0,610	0,350
12	0,610	0,365	0,610	0,345	0,610	0,350
13	0,605	0,345	0,605	0,345	0,605	0,345
14	0,610	0,355	0,605	0,345	0,610	0,355
15	0,605	0,355	0,605	0,340	0,610	0,350
16	0,605	0,355	0,605	0,360	0,615	0,350
17	0,615	0,345	0,615	0,345	0,610	0,350
18	0,605	0,345	0,615	0,345	0,610	0,350
19	0,605	0,355	0,605	0,350	0,610	0,360
20	0,605	0,355	0,605	0,355	0,610	0,355
\bar{x}	0,6080	0,3567	0,6073	0,3485	0,6088	0,3503
SD	0,0041	0,0069	0,0038	0,0054	0,0032	0,0057
KV	0,7	1,9	0,6	1,6	0,5	1,6

Hasil Uji Keseragaman Ukuran Formula 3

No	Replikasi I		Replikasi II		Replikasi III	
	Diameter (cm)	Tebal (cm)	Diameter (cm)	Tebal (cm)	Diameter (cm)	Tebal (cm)
1	0,610	0,355	0,605	0,345	0,605	0,360
2	0,605	0,345	0,605	0,355	0,605	0,345
3	0,610	0,355	0,605	0,350	0,605	0,355
4	0,610	0,340	0,605	0,365	0,605	0,355
5	0,615	0,355	0,610	0,350	0,615	0,345
6	0,610	0,360	0,610	0,355	0,615	0,355
7	0,610	0,350	0,605	0,345	0,610	0,365
8	0,605	0,365	0,610	0,355	0,615	0,345
9	0,610	0,355	0,605	0,340	0,605	0,345
10	0,610	0,365	0,605	0,345	0,615	0,345
11	0,610	0,345	0,605	0,345	0,610	0,360
12	0,610	0,350	0,610	0,345	0,605	0,355
13	0,615	0,355	0,605	0,365	0,610	0,345
14	0,605	0,345	0,615	0,345	0,610	0,355
15	0,610	0,345	0,610	0,350	0,605	0,355
16	0,610	0,340	0,615	0,355	0,605	0,350
17	0,610	0,355	0,615	0,340	0,605	0,365
18	0,610	0,355	0,605	0,345	0,615	0,360
19	0,605	0,345	0,610	0,345	0,610	0,335
20	0,605	0,360	0,610	0,355	0,610	0,340
\bar{x}	0,6093	0,3520	0,6083	0,3498	0,6090	0,3518
SD	0,003	0,008	0,004	0,007	0,004	0,008
KV	0,5	2,1	0,6	2,0	0,7	2,4

Hasil Uji Keseragaman Ukuran Formula 4

No	Replikasi I		Replikasi II		Replikasi III	
	Diameter (cm)	Tebal (cm)	Diameter (cm)	Tebal (cm)	Diameter (cm)	Tebal (cm)
1	0,610	0,355	0,610	0,355	0,605	0,360
2	0,605	0,365	0,610	0,365	0,605	0,355
3	0,605	0,350	0,605	0,370	0,610	0,360
4	0,605	0,365	0,610	0,350	0,605	0,350
5	0,610	0,365	0,610	0,375	0,615	0,350
6	0,605	0,355	0,605	0,365	0,605	0,365
7	0,605	0,365	0,605	0,345	0,615	0,365
8	0,615	0,375	0,605	0,350	0,610	0,350
9	0,610	0,375	0,610	0,355	0,610	0,355
10	0,610	0,350	0,605	0,375	0,615	0,350
11	0,610	0,360	0,610	0,360	0,615	0,375
12	0,610	0,370	0,610	0,350	0,605	0,375
13	0,610	0,375	0,610	0,355	0,610	0,355
14	0,605	0,370	0,615	0,370	0,605	0,350
15	0,615	0,370	0,605	0,350	0,610	0,370
16	0,610	0,375	0,610	0,370	0,605	0,360
17	0,610	0,365	0,615	0,365	0,615	0,355
18	0,610	0,365	0,610	0,375	0,610	0,370
19	0,610	0,355	0,605	0,355	0,615	0,355
20	0,610	0,350	0,610	0,350	0,605	0,350
\bar{x}	0,6090	0,3638	0,6088	0,3603	0,6095	0,3588
SD	0,003	0,009	0,003	0,010	0,004	0,009
KV	0,5	2,4	0,5	2,8	0,7	2,4

LAMPIRAN E
HASIL UJI KEKERASAN ODT DOMPERIDONE

No.	Kekerasan ODT Domperidone (Kgf)											
	Formula 1			Formula 2			Formula 3			Formula 4		
	I	II	III	I	II	III	I	II	III	I	II	III
1	1,5	2,4	1,5	2,8	2,5	2,3	2,5	2,5	2,8	3,0	3,3	2,3
2	1,9	2,2	2,2	3,1	3,1	2,5	3,6	2,9	2,8	2,5	3,2	2,0
3	1,6	2,4	2,2	3,0	2,8	2,9	3,5	3,4	2,6	3,2	3,1	3,2
4	2,0	2,6	1,9	2,1	2,8	2,0	2,8	2,8	2,7	2,6	3,0	2,5
5	1,8	2,0	1,8	2,4	2,1	2,2	3,7	3,2	2,5	2,4	2,6	3,2
6	2,6	2,5	2,0	2,2	2,8	2,1	2,4	3,4	3,2	2,8	2,5	2,4
7	2,1	2,5	1,7	2,0	2,6	2,3	3,5	3,3	3,5	2,0	3,1	2,8
8	2,0	3,0	2,1	2,2	3,0	2,6	2,8	3,6	3,6	2,4	2,9	2,5
9	2,3	2,2	1,5	2,4	2,5	2,2	2,6	3,6	2,8	2,4	2,7	2,4
10	2,4	2,6	2,0	2,2	2,3	2,6	3,6	3,1	3,3	2,6	2,3	2,8
\bar{x}	2,02	2,44	1,89	2,44	2,65	2,37	3,1	3,18	2,98	2,59	2,87	2,61
SD	0,35	0,28	0,26	0,39	0,31	0,28	0,52	0,36	0,39	0,34	0,33	0,39
KV	17,12	11,30	13,76	15,95	11,70	11,61	16,86	11,27	13,03	13,18	11,50	14,83

LAMPIRAN F
HASIL UJI KERAPUHAN ODT DOMPERIDONE

Formula	Replikasi	Berat awal (gram)	Berat akhir (gram)	Kerapuhan (%)	X \square	SD	KV
1	I	2,12	2,10	1,42			
	II	2,07	2,05	1,45	1,43	0,02	1,27
	III	2,11	2,09	1,42			
2	I	2,04	2,02	0,98			
	II	2,01	1,99	1,00	1,00	0,02	2,31
	III	1,95	1,93	1,03			
3	I	2,02	1,99	0,50			
	II	2,01	2,00	0,50	0,50	0,00	0,50
	III	2	1,99	0,50			
4	I	2,03	2,01	0,99			
	II	2,07	2,05	0,97	0,97	0,01	1,02
	III	2,06	2,04	0,97			

LAMPIRAN G
HASIL UJI WAKTU HANCUR ODT DOMPERIDONE

No.	Waktu Hancur ODT Domperidone (detik)											
	Formula 1			Formula 2			Formula 3			Formula 4		
1	35	28	32	16	15	17	49	51	52	31	27	28
2	39	38	29	18	14	18	51	44	47	30	27	25
3	37	34	35	16	18	14	45	38	46	26	24	31
4	39	33	38	20	17	15	47	52	38	29	23	24
5	37	35	37	22	18	19	40	39	41	25	26	29
\bar{x}	37,4	33,6	34,2	18,4	16,4	16,6	46,4	44,8	44,8	28,2	25,4	27,4
SD	1,67	3,65	3,70	2,61	1,82	2,07	4,22	6,53	5,45	2,59	1,82	2,88
KV	4,47	10,85	1082	14,17	11,08	12,49	9,09	14,59	12,16	9,18	7,15	10,51

LAMPIRAN H

HASIL UJI WAKTU PEMBASAHAAN DAN RASIO ABSORBSI AIR ODT DOMPERIDONE

Hasil Uji Waktu Pembasahan dan Rasio Absorpsi Air Formula 1

Waktu Pembasahan dan Rasio Absorpsi Air					
Rep.	No.	Wb	Wa	Waktu Pembasahan (detik)	Rasio Absorpsi Air (%)
I	1	103,3	138,2	25	33,79
	2	105,6	149,0	35	41,10
	3	106,5	146,8	39	37,84
	4	101,6	136,5	36	34,35
	5	102,9	136,7	35	32,85
	6	104,1	142,6	28	36,98
	\bar{x}	104,00	141,63	33,00	36,15
II	SD	1,80	5,37	5,33	3,09
	KV	1,74	3,79	16,15	8,55
	1	106,9	147,8	30	38,26
	2	101,5	132,8	36	30,84
	3	107,7	142,0	34	31,85
	4	106,8	149,8	41	40,26
	5	100,5	134,1	36	33,43
III	6	104,8	147,2	32	40,46
	\bar{x}	104,70	142,28	34,83	35,85
	SD	3,04	7,32	3,82	4,32
	KV	2,90	5,15	10,96	12,06
	1	102,2	143,4	36	40,31
	2	102,0	146,0	35	43,14
	3	107,2	139,8	43	30,41
	4	100,5	141,8	34	41,09
	5	102,0	140,5	42	37,75
	6	101,8	137,4	33	34,97
	\bar{x}	102,62	141,48	37,17	37,95
	SD	2,33	2,99	4,26	4,65
	KV	2,27	2,11	11,47	12,26

Keterangan: Wb=berat tablet sebelum terbasahi

Wa=berat tablet setelah terbasahi

Hasil Uji Waktu Pembasahan dan Rasio Absorpsi Air Formula 2

Waktu Pembasahan dan Rasio Absorpsi Air					
Rep.	No.	Wb	Wa	Waktu Pembasahan (detik)	Rasio Absorpsi Air (%)
I	1	101,5	145,6	23	43,45
	2	103,8	157,5	25	51,73
	3	106,5	148,9	18	39,81
	4	104,6	149,2	22	42,64
	5	104,2	152,6	24	46,45
	6	102,0	146,1	22	43,24
	\bar{x}	103,77	149,98	22,33	44,55
II	SD	1,82	4,46	2,42	4,11
	KV	1,76	2,97	10,85	9,21
	1	99,1	139,0	18	40,26
	2	99,9	140,4	16	40,54
	3	97,7	147,1	22	50,56
	4	97,1	150,6	23	55,10
	5	101,5	144,6	22	42,46
III	6	102,4	145,0	21	41,60
	\bar{x}	99,62	144,45	20,33	45,09
	SD	2,08	4,27	2,73	6,22
	KV	2,09	2,96	13,44	13,79
	1	100,8	161,0	30	59,72
	2	95,7	139,5	24	45,77
	3	100,2	135,7	22	35,43
	4	93,7	145,1	24	54,86
	5	96,0	155,3	26	61,77
	6	95,2	144,4	22	51,68
	\bar{x}	96,93	146,83	24,67	51,54
	SD	2,88	9,58	3,01	9,75
	KV	2,97	6,53	12,21	18,92

Keterangan: Wb=berat tablet sebelum terbasahi
 Wa=berat tablet setelah terbasahi

Hasil Uji Waktu Pembasahan dan Rasio Absorpsi Air Formula 3

Waktu Pembasahan dan Rasio Absorpsi Air					
Rep.	No.	Wb	Wa	Waktu Pembasahan (detik)	Rasio Absorpsi Air (%)
I	1	95,7	135,5	43	41,59
	2	103,0	138,1	39	34,08
	3	102,5	146,4	50	42,83
	4	98,0	134,1	45	36,84
	5	101,8	136,9	51	34,48
	6	95,4	132,3	42	38,68
	\bar{x}	99,40	137,22	45,00	38,08
II	SD	3,46	4,94	4,69	3,63
	KV	3,48	3,60	10,42	9,52
	1	102,4	150,5	47	46,97
	2	102,7	143,2	45	39,44
	3	99,3	129,6	50	30,51
III	4	104,7	142,2	43	35,82
	5	98,5	131,5	46	33,50
	6	103,2	148,6	40	43,99
	\bar{x}	101,80	140,93	45,17	38,37
	SD	2,39	8,65	3,43	6,30
	KV	2,35	6,14	7,59	16,43
	1	101,7	143,6	41	41,20
	2	102,5	153,5	45	49,76
	3	101,5	149,2	42	47,00
	4	101,9	132,2	48	29,74
	5	102,0	144,1	40	41,27
	6	103,7	141,1	45	36,07
	\bar{x}	102,22	143,95	43,50	40,84
	SD	0,80	7,28	3,02	7,26
	KV	0,78	5,06	6,93	17,79

Keterangan: Wb=berat tablet sebelum terbasahi
 Wa=berat tablet setelah terbasahi

Hasil Uji Waktu Pembasahan dan Rasio Absorpsi Air Formula 4

Waktu Pembasahan dan Rasio Absorpsi Air					
Rep.	No.	Wb	Wa	Waktu Pembasahan (detik)	Rasio Absorpsi Air (%)
I	1	101,9	149,6	30	46,81
	2	104,4	151,5	28	45,11
	3	102,7	137,7	25	34,08
	4	102,2	143,2	27	40,12
	5	101,3	150,3	30	48,37
	6	102,3	136,9	24	33,82
	\bar{x}	102,47	144,87	27,33	41,39
	SD	1,06	6,54	2,50	6,39
	KV	1,03	4,51	9,16	15,45
II	1	101,4	143,9	31	41,91
	2	105,2	166,4	26	58,17
	3	100,1	151,2	33	51,05
	4	104,3	160,0	38	53,40
	5	106,4	149,4	25	40,41
	6	101,1	157,5	32	55,79
	\bar{x}	103,08	154,73	30,83	50,12
	SD	2,55	8,12	4,79	7,35
	KV	2,48	5,25	15,54	14,67
III	1	108,8	155,4	34	42,83
	2	104,3	143,9	26	37,97
	3	106,3	164,8	40	55,03
	4	107,7	152,6	32	41,69
	5	104,2	142,5	26	36,76
	6	106,8	150,3	32	40,73
	\bar{x}	106,35	151,58	31,67	42,50
	SD	1,84	8,17	5,28	6,55
	KV	1,73	5,39	16,67	15,41

Keterangan: Wb=berat tablet sebelum terbasahi
 Wa=berat tablet setelah terbasahi

LAMPIRAN I
HASIL UJI STABILITAS ODT DOMPERIDONE

No.	Waktu Hancur ODT Domperidone (detik)											
	Formula 1			Formula 2			Formula 3			Formula 4		
	I	II	III	I	II	III	I	II	III	I	II	III
1	29	28	32	14	12	14	41	42	38	19	20	20
2	32	33	29	14	14	13	47	43	47	17	18	18
3	29	30	26	15	13	11	42	40	47	18	17	17
4	30	34	27	12	12	12	47	45	44	20	18	19
5	28	29	30	13	12	14	40	47	46	20	16	16
\bar{x}	29,6	30,8	28,8	13,4	12,6	12,8	43,4	43,4	44,4	18,8	17,8	18,0
SD	1,52	2,59	2,39	0,9	0,89	1,30	3,36	2,70	3,78	1,30	1,48	1,58
KV	5,12	8,40	8,29	0,1	7,10	10,19	7,75	6,23	8,52	6,94	8,33	8,78

No.	Waktu Pembasahan ODT Domperidone (detik)											
	Formula 1			Formula 2			Formula 3			Formula 4		
	I	II	III	I	II	III	I	II	III	I	II	III
1	30	31	28	18	15	15	38	45	37	24	22	19
2	31	34	32	17	15	15	48	45	45	23	19	20
3	34	33	38	19	16	12	41	48	40	23	23	23
4	35	35	33	16	17	17	42	42	42	22	21	22
5	33	31	36	17	14	17	44	43	43	25	23	21
6	32	30	36	15	14	16	39	38	45	22	23	23
\bar{x}	32,5	32,3	33,8	17,0	15,2	15,3	42,0	43,5	42,0	23,2	21,8	21,3
SD	1,87	1,97	3,60	1,41	1,17	1,86	3,63	3,39	3,10	1,17	1,60	1,63
KV	5,76	6,08	10,64	8,32	7,71	12,14	8,65	7,80	7,38	5,05	7,34	7,65

LAMPIRAN J
HASIL UJI PENETAPAN KADAR ODT DOMPERIDONE

14
1

Formula	Rep.	Abs.	Csamplel ($\mu\text{g/ml}$)	W tablet rata-rata (mg)	W sampel (mg)	Cteoritis ($\mu\text{g/ml}$)	Kadar (%)	\bar{X}	SD	KV (%)	
1	I	0,251	7,79	108,1	100,5	7,44	104,75	103,19	2,00	1,94	
	II	0,248	7,68	105,7	100,6	7,61	100,93				
	III	0,263	8,21	102,1	100,9	7,90	103,91				
2	I	0,253	7,86	103,7	101,0	7,79	100,84	99,89	0,83	0,83	
	II	0,258	8,04	98,2	99,2	8,08	99,47				
	III	0,262	8,18	97,5	100,3	8,23	99,36				
1	3	I	0,255	7,93	101,2	100,8	7,97	99,50	99,41	1,79	1,80
		II	0,26	8,11	100,3	100,5	8,01	101,15			
		III	0,255	7,93	98,6	100,2	8,13	97,58			
4	I	0,248	7,68	102,3	100,2	7,83	98,08	99,91	1,59	1,59	
	II	0,252	7,82	104,0	100,8	7,75	100,90				
	III	0,249	7,72	105,4	100,9	7,66	100,76				
Pembanding 1	1	0,209	6,30	119,8	99,8	6,66	94,50	96,50	1,78	1,85	
	2	0,211	6,37	123,4	100,3	6,50	97,95				
	3	0,214	6,47	121,1	101,0	6,67	97,04				
Pembanding 2	1	0,229	7,00	121,5	100,3	6,60	106,06	103,05	2,62	2,55	
	2	0,213	6,44	125,4	99,7	6,36	101,24				
	3	0,216	6,55	124,6	100,1	6,43	101,84				

Keterangan:
 Pembanding 1 = tablet generik domperidone
 Pembanding 2 = ODT domperidone dengan nama dagang

LAMPIRAN K

HASIL UJI DISOLUSI ODT DOMPERIDONE PADA t = 30 MENIT

Hasil Uji Disolusi Tablet Formula 1

Rep.	t (menit)	A	C ($\mu\text{g/ml}$)	Wt (mg)	% obat terlepas	AUC ($\mu\text{g menit / ml}$)
I	0,5	0,187	5,53	5,0	47,49	1,24
	1	0,292	9,24	8,3	79,36	3,32
	2	0,315	10,05	9,0	86,35	8,68
	4	0,318	10,16	9,1	87,26	18,18
	6	0,308	9,80	8,8	84,22	17,96
	8	0,299	9,48	8,5	81,49	17,36
	10	0,305	9,70	8,7	83,31	17,26
	15	0,303	9,63	8,7	82,70	43,47
	20	0,304	9,66	8,7	83,01	43,39
	25	0,296	9,38	8,4	80,58	42,84
	30	0,295	9,34	8,4	80,28	42,12
						□ AUC 255,84
						% ED 81,42
II	0,5	0,224	6,83	6,2	60,94	1,54
	1	0,325	10,40	9,4	92,76	3,88
	2	0,343	11,04	9,9	98,43	9,65
	4	0,347	11,18	10,1	99,69	20,00
	6	0,335	10,76	9,7	95,91	19,74
	8	0,339	10,90	9,8	97,17	19,49
	10	0,338	10,86	9,8	96,86	19,58
	15	0,338	10,86	9,8	96,86	48,88
	20	0,336	10,79	9,7	96,23	48,72
	25	0,336	10,79	9,7	96,23	48,56
	30	0,335	10,76	9,7	95,91	48,48
						□ AUC 288,52
						% ED 95,29

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
III	0,5	0,234	7,19	6,5	61,75	1,62
	1	0,322	10,30	9,3	88,47	3,93
	2	0,348	11,22	10,1	96,37	9,68
	4	0,353	11,39	10,3	97,88	20,35
	6	0,347	11,18	10,1	96,06	20,32
	8	0,332	10,65	9,6	91,51	19,65
	10	0,342	11,00	9,9	94,55	19,49
	15	0,34	10,93	9,8	93,94	49,36
	20	0,337	10,83	9,7	93,03	48,96
	25	0,337	10,83	9,7	93,03	48,72
	30	0,335	10,76	9,7	92,42	48,56
						□ AUC 290,63
						% ED 93,23

Hasil Uji Disolusi Tablet Formula 2

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
I	0,5	0,181	5,31	4,8	47,43	1,20
	1	0,306	9,73	8,8	86,85	3,39
	2	0,329	10,54	9,5	94,11	9,12
	4	0,344	11,07	10,0	98,84	19,46
	6	0,339	10,90	9,8	97,26	19,77
	8	0,339	10,90	9,8	97,26	19,62
	10	0,335	10,76	9,7	96,00	19,49
	15	0,335	10,76	9,7	96,00	48,40
	20	0,336	10,79	9,7	96,31	48,48
	25	0,335	10,76	9,7	96,00	48,48
	30	0,334	10,72	9,6	95,68	48,32
						□ AUC 285,73
						% ED 94,45

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
II	0,5	0,22	6,69	6,0	60,55	1,51
	1	0,325	10,40	9,4	94,12	3,85
	2	0,33	10,58	9,5	95,72	9,44
	4	0,342	11,00	9,9	99,56	19,42
	6	0,337	10,83	9,7	97,96	19,65
	8	0,336	10,79	9,7	97,64	19,46
	10	0,334	10,72	9,6	97,00	19,36
	15	0,328	10,51	9,5	95,08	47,77
	20	0,325	10,40	9,4	94,12	47,05
	25	0,32	10,23	9,2	92,53	46,42
	30	0,291	9,20	8,3	83,25	43,71
					□ AUC	277,63
					% ED	93,04
III	0,5	0,212	6,41	5,8	58,06	1,44
	1	0,321	10,26	9,2	92,95	3,75
	2	0,334	10,72	9,6	97,11	9,44
	4	0,34	10,93	9,8	99,03	19,49
	6	0,327	10,47	9,4	94,87	19,27
	8	0,327	10,47	9,4	94,87	18,85
	10	0,322	10,30	9,3	93,27	18,69
	15	0,322	10,30	9,3	93,27	46,34
	20	0,314	10,01	9,0	90,71	45,70
	25	0,315	10,05	9,0	91,03	45,14
	30	0,298	9,45	8,5	85,59	43,87
					□ AUC	271,98
					% ED	91,25

Hasil Uji Disolusi Tablet Formula 3

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
I	0,5	0,144	4,01	3,6	36,25	0,90
	1	0,291	9,20	8,3	83,23	2,97
	2	0,327	10,47	9,4	94,74	8,85
	4	0,343	11,04	9,9	99,85	19,36
	6	0,33	10,58	9,5	95,70	19,46
	8	0,333	10,69	9,6	96,66	19,14
	10	0,336	10,79	9,7	97,62	19,33
	15	0,326	10,44	9,4	94,42	47,77
	20	0,324	10,37	9,3	93,78	46,81
	25	0,319	10,19	9,2	92,18	46,26
	30	0,313	9,98	9,0	90,26	45,38
\square AUC						276,23
<% ED						92,54
II	0,5	0,147	4,11	3,7	36,60	0,93
	1	0,295	9,34	8,4	83,13	3,03
	2	0,332	10,65	9,6	94,76	9,00
	4	0,335	10,76	9,7	95,71	19,27
	6	0,333	10,69	9,6	95,08	19,30
	8	0,334	10,72	9,6	95,39	19,27
	10	0,334	10,72	9,6	95,39	19,30
	15	0,331	10,61	9,6	94,45	48,01
	20	0,327	10,47	9,4	93,19	47,45
	25	0,326	10,44	9,4	92,88	47,05
	30	0,325	10,40	9,4	92,56	46,89
\square AUC						279,47
<% ED						92,10

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
III	0,5	0,176	5,14	4,6	47,39	1,16
	1	0,301	9,55	8,6	88,13	3,31
	2	0,329	10,54	9,5	97,25	9,04
	4	0,333	10,69	9,6	98,56	19,11
	6	0,334	10,72	9,6	98,88	19,27
	8	0,337	10,83	9,7	99,86	19,39
	10	0,332	10,65	9,6	98,23	19,33
	15	0,334	10,72	9,6	98,88	48,08
	20	0,325	10,40	9,4	95,95	47,53
	25	0,322	10,30	9,3	94,97	46,57
	30	0,322	10,30	9,3	94,97	46,34
						□ AUC 279,12
						% ED 95,35

Hasil Uji Disolusi Tablet Formula 4

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
I	0,5	0,201	6,02	5,4	54,47	1,35
	1	0,279	8,78	7,9	79,40	3,33
	2	0,341	10,97	9,9	99,21	8,89
	4	0,337	10,83	9,7	97,94	19,62
	6	0,332	10,65	9,6	96,34	19,33
	8	0,331	10,61	9,6	96,02	19,14
	10	0,325	10,40	9,4	94,10	18,92
	15	0,323	10,33	9,3	93,46	46,65
	20	0,319	10,19	9,2	92,18	46,18
	25	0,314	10,01	9,0	90,58	45,46
	30	0,313	9,98	9,0	90,26	44,98
						□ AUC 273,84
						% ED 91,74

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
II	0,5	0,181	5,31	4,8	47,29	1,20
	1	0,226	6,90	6,2	61,44	2,75
	2	0,347	11,18	10,1	99,48	8,14
	4	0,348	11,22	10,1	99,79	20,16
	6	0,345	11,11	10,0	98,85	20,09
	8	0,345	11,11	10,0	98,85	20,00
	10	0,347	11,18	10,1	99,48	20,06
	15	0,337	10,83	9,7	96,34	49,52
	20	0,323	10,33	9,3	91,93	47,61
	25	0,321	10,26	9,2	91,30	46,34
	30	0,319	10,19	9,2	90,68	46,02
					□ AUC	281,87
					% ED	92,89
III	0,5	0,164	4,71	4,2	43,48	1,06
	1	0,31	9,87	8,9	91,06	3,28
	2	0,324	10,37	9,3	95,62	9,11
	4	0,337	10,83	9,7	99,86	19,07
	6	0,334	10,72	9,6	98,88	19,39
	8	0,328	10,51	9,5	96,93	19,11
	10	0,337	10,83	9,7	99,86	19,20
	15	0,328	10,51	9,5	96,93	48,01
	20	0,326	10,44	9,4	96,27	47,13
	25	0,324	10,37	9,3	95,62	46,81
	30	0,319	10,19	9,2	93,99	46,26
					□ AUC	278,43
					% ED	95,11

Hasil Uji Disolusi Tablet Pembanding 1

Rep	t (menit)	Abs.	Kons. (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg.menit/mL)
I	0,5	0,167	4,82	4,3	45,86	1,08
	1	0,204	6,12	5,5	58,30	2,46
	2	0,306	9,72	8,7	92,59	7,13
	4	0,312	9,93	8,9	94,60	17,69
	6	0,322	10,29	9,3	97,97	18,20
	8	0,334	10,71	9,6	102,00	18,90
	10	0,321	10,25	9,2	97,63	18,87
	15	0,327	10,46	9,4	99,65	46,61
	20	0,307	9,76	8,8	92,92	45,50
	25	0,313	9,97	9,0	94,94	44,39
	30	0,319	10,18	9,2	96,96	45,34
					Σ AUC	266,16
					%ED	93,88
II	0,5	0,117	3,05	2,7	28,03	0,69
	1	0,240	7,39	6,7	67,93	2,35
	2	0,277	8,70	7,8	79,93	7,24
	4	0,310	9,86	8,9	90,63	16,71
	6	0,324	10,36	9,3	95,17	18,20
	8	0,328	10,50	9,4	96,47	18,77
	10	0,320	10,22	9,2	93,88	18,64
	15	0,310	9,86	8,9	90,63	45,18
	20	0,326	10,43	9,4	95,82	45,66
	25	0,318	10,15	9,1	93,23	46,29
	30	0,322	10,29	9,3	94,52	45,97
					Σ AUC	265,70
					%ED	90,42

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
III	0,5	0,148	4,15	3,7	38,44	0,93
	1	0,227	6,93	6,2	64,31	2,49
	2	0,248	7,67	6,9	71,18	6,57
	4	0,285	8,98	8,1	83,29	14,99
	6	0,327	10,46	9,4	97,04	17,50
	8	0,328	10,50	9,4	97,37	18,87
	10	0,314	10,00	9,0	92,79	18,45
	15	0,323	10,33	9,3	93,46	46,65
	20	0,306	9,72	8,7	90,17	45,26
	25	0,319	10,18	9,2	94,42	44,78
	30	0,326	10,43	9,4	96,72	46,37
					Σ AUC	262,11
					%ED	90,04

Hasil Uji Disolusi Tablet Pembanding 2

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
I	0,5	0,145	4,04	3,6	34,28	0,91
	1	0,284	8,95	8,1	75,91	2,92
	2	0,342	10,99	9,9	93,28	8,97
	4	0,351	11,31	10,2	95,98	20,07
	6	0,358	11,56	10,4	98,08	20,58
	8	0,348	11,20	10,1	95,08	20,49
	10	0,333	10,68	9,6	90,59	19,69
	15	0,343	11,03	9,9	93,58	48,83
	20	0,350	11,28	10,1	95,68	50,18
	25	0,341	10,96	9,9	92,99	50,02
	30	0,342	10,99	9,9	93,28	49,39
					Σ AUC	292,06
					%ED	91,79

Rep	t (menit)	A	C (μg/ml)	Wt (mg)	% obat terlepas	AUC (μg menit / ml)
II	0,5	0,196	5,84	5,3	51,91	1,31
	1	0,208	6,26	5,6	55,68	2,72
	2	0,291	9,19	8,3	81,72	6,96
	4	0,352	11,35	10,2	100,86	18,48
	6	0,346	11,13	10,0	98,98	20,23
	8	0,338	10,85	9,8	96,47	19,79
	10	0,336	10,78	9,7	95,84	19,47
	15	0,341	10,96	9,9	97,41	48,91
	20	0,331	10,60	9,5	94,27	48,51
	25	0,334	10,71	9,6	95,21	47,96
	30	0,326	10,43	9,4	92,70	47,56
					Σ AUC	281,91
					%ED	92,82
III	0,5	0,130	3,51	3,2	31,02	0,79
	1	0,241	7,43	6,7	65,64	2,46
	2	0,341	10,96	9,9	96,84	8,27
	4	0,359	11,59	10,4	102,45	20,30
	6	0,348	11,20	10,1	99,02	20,52
	8	0,352	11,35	10,2	100,27	20,30
	10	0,347	11,17	10,1	98,71	20,26
	15	0,337	10,82	9,7	95,59	49,47
	20	0,344	11,06	10,0	97,77	49,23
	25	0,312	9,93	8,9	87,79	47,24
	30	0,331	10,60	9,5	93,72	46,21
					Σ AUC	285,05
					%ED	93,30

LAMPIRAN L

CONTOH PERHITUNGAN

Contoh perhitungan indeks kompresibilitas:

Formula I :

$$\text{Berat gelas} = 105,0340 \text{ g (W}_1\text{)}$$

$$\text{Berat gelas + granul} = 151,5084 \text{ g (W}_2\text{)}$$

$$V_1 = 100 \text{ ml}, V_2 = 85 \text{ ml}$$

$$\text{Bj nyata} = \frac{(W_2 - W_1)}{V_1} = \frac{(151,5084 - 105,0340)}{100} = 0,4647 \text{ g/ml}$$

$$\text{Bj mampat} = \frac{(W_2 - W_1)}{V_2} = \frac{(151,5084 - 105,0340)}{85} = 0,5468 \text{ g/ml}$$

$$\% \text{ Carr's Index} = \left(1 - \frac{\text{Bj.nyata}}{\text{Bj.mampat}} \right) \times 100\% = 15\%$$

$$\text{Hausner Ratio} = \frac{\text{bjmampat}}{\text{bjnyata}} = 1,18$$

Contoh perhitungan akurasi & presisi:

Kons. (%)	Massa (mg)	Abs.	Kons. ($\mu\text{g/ml}$)	Teoritis ($\mu\text{g/ml}$)	Perolehan Kembali (%)
100	101,5	0,262	8,18	8,14	100,45

$$\text{Absorbansi} = 0,262 \rightarrow y = 0,0283x + 0,0306$$

$$\text{Konsentrasi sampel (x)} = 8,18 \text{ ppm}$$

$$\text{Berat domperidone} = 70,2 \text{ mg}$$

$$\text{Berat matriks} = 630,1 \text{ mg}$$

$$\text{Berat sampel} = 101,5 \text{ mg}$$

$$\text{Konsentrasi teoritis} =$$

$$\frac{W_{\text{sampel}}}{(W_{\text{domperidone}} + W_{\text{matriks}})} \times W_{\text{domperidone}} \times FP$$

$$= \frac{100,4}{(70,2 + 630,1)} \times 70 \times 10^3 \times \left(\frac{1}{250} \times \frac{2}{10}\right)$$

$$= 8,14 \text{ ppm}$$

$$\% \text{ Perolehan Kembali} = \frac{\text{Konsentrasi sampel}}{\text{Konsentrasi teoritis}} \times 100\%$$

$$= \frac{8,14}{8,14} \times 100\%$$

$$= 100,45\%$$

$$\% \text{ KV} = \frac{SD}{X} \times 100\%$$

$$= \frac{0,55}{0,52} \times 100\%$$

$$= 0,55\%$$

Contoh perhitungan penetapan kadar:

Formula 1 replikasi II

Abs.	Kons. Sampel ($\mu\text{g/ml}$)	W Tablet Rata-rata (mg)	W Sampel (mg)	Kons. Teoritis ($\mu\text{g/ml}$)	Kadar (%)
0,248	7,68	105,74	100,6	7,61	100,93

$$\text{Absorbansi} = 0,248 \rightarrow y = 0,0283x + 0,0306$$

$$\text{Konsentrasi sampel (x)} = 7,68 \text{ ppm}$$

$$\text{Berat tablet rata-rata} = 105,74 \text{ g}$$

$$\text{Berat sampel} = 100,6 \text{ mg}$$

$$\text{Berat Domperidone} = 10 \text{ mg}$$

$$\text{Konsentrasi teoritis} = \frac{W_{\text{sampel}}}{W_{\text{tablet rata-rata}}} \times W_{\text{domperidone}} \times FP$$

$$= \frac{100,6}{105,74} \times 10 \times 10^3 \times \left(\frac{1}{250} \times \frac{2}{10}\right) = 7,61 \text{ ppm}$$

$$\begin{aligned}\% \text{ Perolehan Kembali} &= \frac{\text{konsentrasi sampel}}{\text{konsentrasi teoritis}} \times 100\% \\ &= \frac{7,68}{7,61} \times 100\% = 100,93\%\end{aligned}$$

$$\begin{aligned}\% \text{ KV} &= \frac{SD}{X} \times 100\% \\ &= \frac{2}{108,19} \times 100\% = 1,94\%\end{aligned}$$

Contoh perhitungan % obat terlepas:

Formula 1 replikasi II pada t = 30 menit

$$\text{Absorbansi} = 0,335 \rightarrow y = 0,0283x + 0,0306$$

$$Csampel (x) = 10,76 \mu\text{g/ml}$$

$$\begin{aligned}Wt &= (900/1000 \times \text{konsentrasi sampel}) \\ &= (900/1000 \times 10,76) \\ &= 9,7 \text{ mg}\end{aligned}$$

$$\% \text{ Obat Terlepas} = \frac{Wt}{\frac{PK}{100} \times \text{dosis}} \times 100\%$$

Formula I replikasi 2 pada t = 30 menit

$$\% \text{ Obat Terlepas} = \frac{9,7}{\frac{100,93}{100} \times 10} \times 100\% = 95,91\%$$

Contoh perhitungan AUC pada disolusi:

Rumus:

Formula I replikasi 1

$$tn-1 = 30 \text{ menit} \quad Wtn-1 = 9,7 \text{ mg}$$

$$tn = 25 \text{ menit} \quad Wtn = 9,7 \text{ mg}$$

$$AUC = \frac{9,7 + 9,7}{2} \times (30 - 25) = 48,48$$

Luas persegi = 30 x penetapan kadar x dosis domperidone

$$= 30 \times 100,93\% \times 10 \text{ mg}$$

$$= 302,7929$$

% ED Formula 1 replikasi II = $(\sum \text{AUC} / \text{luas persegi}) \times 100\%$

$$= (48,48/302,7929) \times 100\%$$

$$= 95,29 \%$$

LAMPIRAN M
SERTIFIKAT ANALISIS BAHAN

DOMPERIDONE

 VASUDHA PHARMA CHEM. LTD	<p style="text-align: center;">VASUDHA PHARMA CHEM LIMITED 78/A, VENGAL RAO NAGAR, HYDERABAD-38 ANDHRA PRADESH, INDIA PHONE:+91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576 E-MAIL: vasudha@vasudhapharma.com, Website: www.vasudhapharma.com</p>
---	---

CERTIFICATE OF ANALYSIS

Name of the product	: DOMPERIDONE	Page No.	: 1 of 2
Batch Number	: BDOM/1106090	A.R.No	: BDOM/11090
Manufacturing Date	: JUN 2011	Expiry Date	: MAY 2016
Dispatch Quantity	: 30.0 Kg	Analyzed on	: 18/06/2011
Customer Name/ code	: PT Taterasa		

S.No	TEST		RESULT	SPECIFICATION		
1.0 CHARACTERS						
1.1	Appearance		A white powder	A white or almost white powder.		
1.2	Solubility		Complies	Practically insoluble in water, soluble in dimethyl formamide, slightly soluble in alcohol and in methanol		
2.0 Identification						
FIRST IDENTIFICATION						
A	Melting Point (°)	244.5	244 to 248			
B	IR Identification (KBr disc)	Complies	The spectrum obtained with the substance to be examined correspond in position and relative size to those in the spectrum obtained with Domperidone reference standard(Working standard)			
SECOND IDENTIFICATION						
C	Thin layer chromatography (TLC)	Complies	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution(a)			
D	Test for non-nitrogen substituted barbiturates	Complies	A violet blue colour and precipitate produces			
3.0 TESTS						
3.1	Appearance of solution	Complies	The solution should be clear and not more intensely coloured than reference solution Y ₆			

PREPARED BY: J. M. D. CHECKED BY: J. M. D. APPROVED BY: V. S. K.
 21/06/2011 21/06/2011 21/06/2011

Works

V/s. VASUDHA PHARMA CHEM LIMITED, Unit-II, Plot No: 79, J.N.Pharma City, Thanam Village, Parwada Mandalam, Visakhapatnam - 531 021,
 Andhra Pradesh, India.





VASUDHA PHARMA CHEM LTD

VASUDHA PHARMA CHEM LIMITED
78/A, VENGAL RAO NAGAR, HYDERABAD-38
ANDHRA PRADESH, INDIA
PHONE:+91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576
E-MAIL: vasudha@vasudhapharma.com, Website: www.vasudhapharma.com

CERTIFICATE OF ANALYSIS

Name of the product	: DOMPERIDONE	Page No.	: 1 of 2
Batch Number	: BDOM/1106090	A.R.No	: BDOM/11090
Manufacturing Date	: JUN 2011	Expiry Date	: MAY 2016
Dispatch Quantity	: 30.0 Kg	Analyzed on	: 18/06/2011
Customer Name/ code	: PT Taterasa		

S.No	TEST	RESULT	SPECIFICATION
1.0	CHARACTERS		
1.1	Appearance	A white powder	A white or almost white powder.
1.2	Solubility	Complies	Practically insoluble in water; soluble in dimethyl formamide, slightly soluble in alcohol and in methanol
2.0	Identification		
	FIRST IDENTIFICATION		
A	Melting Point (°)	244.5	244 to 248
B	IR Identification (KBr disc)	Complies	The spectrum obtained with the substance to be examined correspond in position and relative size to those in the spectrum obtained with Domperidone reference standard(Working standard)
	SECOND IDENTIFICATION		
C	Thin layer chromatography (TLC)	Complies	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution(a)
D	Test for non-nitrogen substituted barbiturates	Complies	A violet blue colour and precipitate produces
3.0	TESTS		
3.1	Appearance of solution	Complies	The solution should be clear and not more intensely coloured than reference solution Y ₆

PREPARED BY: Heno CHECKED BY: M.G.P APPROVED BY: V.S
 21/06/2011 21/06/2011 21/06/2011

Works

9/A, VASUDHA PHARMA CHEM LIMITED, Unit-II, Plot No: 79, J.N.Pharma City, Tharam Village, Parwada Mandalam, Visakhapatnam - 531 021, Andhra Pradesh, India.



VASUDHA PHARMA CHEM LIMITED
 78/A, VENGAL RAO NAGAR, HYDERABAD-38
 ANDHRA PRADESH, INDIA
 PHONE:+91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576
 E-MAIL: vasudha@vasudhapharma.com, Website: www.vasudhapharma.com

Name of the product	:	DOMPERIDONE	Page No.	:	2 of 2
Batch Number	:	BDOM/1106090	A.R.No	:	BDOM/11090
Manufacturing Date	:	JUN 2011	Expiry Date	:	MAY 2016
Dispatch Quantity	:	30.0 Kg	Analyzed on	:	18/06/2011
Customer Name/ code	:	PT Taterasa			

S.No	TEST	RESULT	SPECIFICATION
3.2	Heavy metals (ppm)	Less than 20	Not more than 20
3.3	Loss on drying(% ,w/w)	0.34	Not more than 0.5
3.4	Sulphated Ash(% ,w/w)	0.06	Not more than 0.1
3.5	Assay (By titrimetry, %w/w, on dried basis)	99.53	Not less than 99.0 and Not more than 101.0
3.6	Related substances (By HPLC, %)		
	Impurity-A	0.06	Not more than 0.25
	Impurity-B	Not detected	Not more than 0.25
	Impurity-C	Not detected	Not more than 0.25
	Impurity-D	0.14	Not more than 0.25
	Impurity-E	Not detected	Not more than 0.25
	Impurity-F	Not detected	Not more than 0.25
	Unspecified impurities	Not detected	Not more than 0.10
	Total impurity	0.19	Not more than 0.50

REMARKS: The material complies as per the BP specification.



PREPARED BY:	CHECKED BY:	APPROVED BY:
<i>[Signature]</i> 21/06/2011	<i>[Signature]</i> 21/06/2011	<i>[Signature]</i> 21/06/2011

Works

M/s. VASUDHA PHARMA CHEM LIMITED, Unit-II, Plot No: 79, J.N Pharma City, Thanam Village, Parawada Mandalam, Visakhapatnam – 531 021,
 Andhra Pradesh, India.

CROSPOVIDONE

BASF

The Chemical Company

Certificate of Analysis

BASF South East Asia Pte Ltd

Please note that the certificates of analysis are also conveniently available online and around the clock at www.worldaccount.bASF.com

Fax No 006200215452306

PT MEGASETIA AGUNG KIMIA

SUNTER AGUNG PODOMORO TANJUNG PRIOK
14350 JAKARTA UTARA
Indonesia

2011-09-20
Fr. Dr. Nina Dominique Kaeppel
nina.kaeppel@basf.com
+49 621 60-51484
Certificate No 4246
Page 2 of 3

Certificate of Analysis according to DIN 55350-18-4.2.2

Kollidon® CL

40KG PE-Drum, removable head
Purchase Order/Customer Product#
291/07/2011
50000695

Material	50000695
Order	1327640227 000010
Delivery	8027249170 000001
Lot	30074924U0
Lot/City	1800.000 KG
Total	1800.000 KG

Test Parameter	Requirements	UoM	Results
Total aerobic microbial count (TAMC)	Max.: 200	CFU/g	<10
Total combined yeasts/moulds count (TYMC)	Max.: 20	CFU/g	<10

*Test is verified on random samples only.

The product meets the requirements of the following monographs:

"Crosppovidone" of Ph.Eur.7.Edition (Type A). USP34/NF29, JPE 2004

Manufacturer: BASF SE
Carl-Bosch-Str.38
67056 Ludwigshafen
Germany

QC-Reference-No.	11C08256
Production date	07.2011
Release date	22.07.2011
Retest date	07.2014

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.

This is a computer-generated document. No signature is required.

MANITOL



I.C. 1 EELA CERTIFICATE OF ANALYSIS / COMPLIANCE

PAGE 1

PT SIGNA HUSADA

JALAN DAAN MOGOT KM 17

JAKARTA 11840

INDONESIA

PEARLITOL 160 C

CUSTOMER.... SIGNA HUSADA/INDONESIA

450001 D

INVOICE..... MD758A1
TONNAGE..... 18.000 KG
CONTRACT.... F55433L
ORDER..... P.O.100002538
BATCH..... E611T
MANUF&TESTED 14 APRIL 2011

EXPIRY DATE.

01-MAY 2016

E.P./U.S.P.

● DESCRIPTION

MEANING TESTED = ANALYZED
MONITORED = MONITORING PLAN
GUARANTEED = COMPLIANCE DATA

APPEARANCE

CONFORM TESTED

APPEARANCE IN SOLUTION

CONFORM TESTED

LOSS ON DRYING

0,05 TESTED

INFRA-RED

CONFORM TESTED

MELTING POINT

166 TESTED

START OF MELTING

166 TESTED

END OF MELTING

167 TESTED

SPECIFIC ROTATION(BORATE)

+ 23,6 TESTED

SPECIFIC ROT.MOLYBDATE

+ 140,1 TESTED

CONDUCTIVITY

1,0 TESTED

REDUCING SUGARS

CONFORM TESTED

D-MANNITOL BY HPLC

99,2 TESTED

ROQUETTE FRERES, 1, RUE DE LA HAUTE LOGE, 69126 LYON FRANCE
This document has an electronic signature

LAMPIRAN N

TABEL UJI F

TABEL DISTRIBUSI F UNTUK 5% DAN 1%

Baris atas untuk taraf signifikan 5%

Baris bawah untuk taraf signifikan 1%

$V_2 = dk$ penyebut	$V_1 = dk$ pembilang																								
	1	2	3	4	5	6	7	8	9	10	11	12	14	16	20	24	30	40	50	75	100	200	500	∞	
1	161	200	216	225	230	234	237	239	241	242	243	244	245	246	248	249	250	251	252	253	253	254	254	254	
	4052	4999	5403	5625	5764	5859	5928	5961	6022	6056	6082	6106	6142	6169	6208	6234	6258	6286	6302	6323	6334	6352	6361	6366	
2	18,51	19,00	19,16	19,25	19,30	19,33	19,36	19,37	19,38	19,39	19,40	19,41	19,42	19,43	19,44	19,45	19,46	19,47	19,47	19,48	19,49	19,49	19,50	19,50	
	98,49	99,01	99,17	99,25	99,30	99,33	99,34	99,36	97,38	99,40	99,41	99,42	99,43	99,44	99,45	99,46	99,47	99,48	99,49	99,49	99,49	99,50	99,50	99,50	
3	10,13	9,55	9,28	9,12	9,01	8,94	8,88	8,84	8,81	8,78	8,76	8,74	8,71	8,69	8,66	8,64	8,62	8,60	8,58	8,57	8,56	8,54	8,54	8,53	
	34,12	30,81	29,46	28,71	28,24	27,91	27,67	27,49	27,34	27,23	27,13	27,05	26,92	26,83	26,69	26,60	26,50	26,41	26,30	26,27	26,23	26,18	26,14	26,12	
4	7,71	6,94	6,59	6,39	6,26	6,16	6,09	6,04	6,00	5,96	5,93	5,91	5,87	5,84	5,80	5,77	5,74	5,71	5,70	5,68	5,66	5,65	5,64	5,53	
	21,20	18,00	16,69	15,88	15,52	15,21	14,98	14,80	14,66	14,54	14,45	14,37	14,24	14,15	14,02	13,93	13,83	13,74	13,69	13,61	13,57	13,52	13,48	13,46	
5	6,61	5,79	5,41	5,19	5,05	4,95	4,88	4,82	4,78	4,74	4,70	4,68	4,64	4,60	4,56	4,53	4,50	4,46	4,44	4,42	4,40	4,38	4,37	4,36	
	16,26	13,27	12,06	11,39	10,97	10,67	10,45	10,27	10,15	10,05	9,96	9,89	9,77	9,68	9,55	9,47	9,38	9,29	9,24	9,17	9,13	9,07	9,04	9,02	
6	5,99	5,14	4,76	4,53	4,39	4,28	4,21	4,15	4,10	4,06	4,03	4,00	3,96	3,92	3,87	3,84	3,81	3,77	3,75	3,72	3,71	3,69	3,68	3,67	
	13,74	10,92	9,78	9,15	8,75	8,47	8,26	8,10	7,98	7,87	7,79	7,72	7,60	7,52	7,39	7,31	7,23	7,14	7,09	7,02	6,99	6,94	6,90	6,88	
7	5,59	4,74	4,35	4,12	3,97	3,87	3,79	3,73	3,68	3,63	3,60	3,57	3,52	3,49	3,44	3,41	3,38	3,34	3,32	3,29	3,28	3,25	3,24	3,23	
	12,25	9,55	8,45	7,85	7,46	7,19	7,00	6,84	6,71	6,62	6,54	6,47	6,35	6,27	6,15	6,07	5,98	5,90	5,85	5,78	5,75	5,70	5,67	5,65	
8	5,32	4,46	4,07	3,84	3,69	3,58	3,50	3,44	3,39	3,34	3,31	3,28	3,23	3,20	3,15	3,12	3,08	3,05	3,03	3,00	2,98	2,96	2,94	2,93	
	11,26	8,65	7,59	7,01	6,63	6,37	6,19	6,03	5,91	5,82	5,74	5,67	5,56	5,48	5,36	5,28	5,20	5,11	5,06	5,00	4,96	4,91	4,88	4,86	
9	5,12	4,26	3,86	3,63	3,48	3,37	3,29	3,23	3,18	3,13	3,10	3,07	3,02	2,98	2,93	2,90	2,86	2,82	2,80	2,77	2,76	2,73	2,72	2,71	
	10,56	8,02	6,99	6,42	6,06	5,80	5,62	5,47	5,35	5,26	5,18	5,11	5,00	4,92	4,80	4,73	4,61	4,56	4,51	4,45	4,41	4,36	4,33	4,34	

LAMPIRAN O

TABEL UJI r

DEGREES OF FREEDOM (DF)	5 PERCENT	1 PERCENT	DEGREES OF FREEDOM (DF)	5 PERCENT	1 PERCENT
1	.997	1.000	24	.388	.496
2	.950	.990	25	.381	.487
3	.878	.959	26	.374	.478
4	.811	.917	27	.367	.470
5	.754	.874	28	.361	.463
6	.707	.834	29	.355	.456
7	.666	.798	30	.349	.449
8	.632	.765	35	.325	.418
9	.602	.735	40	.304	.393
10	.576	.708	48	.288	.372
11	.553	.684	50	.273	.354
12	.532	.661	60	.250	.325
13	.514	.641	70	.232	.302
14	.497	.623	80	.217	.283
15	.482	.606	90	.205	.267
16	.468	.590	100	.195	.254
17	.456	.575	125	.174	.228
18	.444	.561	150	.159	.208
19	.433	.549	200	.138	.181
20	.423	.537	300	.113	.148
21	.413	.526	400	.098	.128
22	.404	.515	500	.088	.115
23	.396	.505	1000	.062	.081

Dikutip dari: Soedigdo & Soedigdo (1977)

LAMPIRAN P
TABEL UJI LSD (0,05)

k d.k.	2	3	4	5	6	7	8	9	10	11
5	3.64	4.60	5.22	5.67	6.03	6.33	6.58	6.80	6.99	7.17
6	3.46	4.34	4.90	5.30	5.63	5.90	6.12	6.32	6.49	6.65
7	3.34	4.16	4.68	5.06	5.36	5.61	5.82	6.00	6.16	6.30
8	3.26	4.04	4.53	4.89	5.17	5.40	5.60	5.77	5.92	6.05
9	3.20	3.95	4.41	4.76	5.02	5.24	5.43	5.59	5.74	5.87
10	3.15	3.88	4.33	4.65	4.91	5.12	5.30	5.46	5.60	5.72
11	3.11	3.82	4.26	4.57	4.82	5.03	5.20	5.35	5.49	5.61
12	3.08	3.77	4.20	4.51	4.75	4.95	5.12	5.27	5.39	5.51
13	3.06	3.73	4.15	4.45	4.69	4.88	5.05	5.19	5.32	5.43
14	3.03	3.70	4.11	4.41	4.64	4.83	4.99	5.13	5.25	5.36
15	3.01	3.67	4.08	4.37	4.59	4.78	4.94	5.08	5.20	5.31
16	3.00	3.65	4.05	4.33	4.56	4.74	4.90	5.03	5.15	5.26
17	2.98	3.63	4.02	4.30	4.52	4.71	4.86	4.99	5.11	5.21
18	2.97	3.61	3.99	4.28	4.49	4.67	4.82	4.96	5.07	5.17
19	2.96	3.59	3.98	4.25	4.47	4.65	4.79	4.92	5.04	5.14
20	2.95	3.58	3.96	4.23	4.45	4.62	4.77	4.90	5.01	5.11
24	2.92	3.53	3.90	4.17	4.37	4.54	4.68	4.81	4.92	5.01
30	2.89	3.49	3.85	4.10	4.30	4.46	4.60	4.72	4.82	4.92
40	2.86	3.44	3.79	4.04	4.23	4.39	4.52	4.63	4.73	4.82
60	2.83	3.40	3.74	3.98	4.16	4.31	4.44	4.55	4.65	4.73
120	2.80	3.36	3.68	3.92	4.10	4.24	4.36	4.47	4.56	4.64
∞	2.77	3.31	3.63	3.86	4.03	4.17	4.29	4.39	4.47	4.55

Catatan kaki: Dari *Annals of mathematical statistics*. Diulang cetak seizin penerbit, The Institute of Mathematical Statistics.

Sumber: Schefler (1987).

LAMPIRAN Q

TABEL UJI T

v	α				
	0.10	0.05	0.025	0.01	0.005
1	3.078	6.314	12.706	31.821	63.657
2	1.886	2.920	4.303	6.965	9.925
3	1.638	2.353	3.182	4.451	5.841
4	1.533	2.132	2.776	3.747	4.604
5	1.476	2.015	2.561	3.365	4.012
6	1.440	1.943	2.447	3.143	3.707
7	1.415	1.895	2.365	2.998	3.499
8	1.397	1.860	2.306	2.896	3.355
9	1.383	1.833	2.262	2.821	3.250
10	1.372	1.812	2.228	2.764	3.169
11	1.363	1.796	2.201	2.718	3.106
12	1.356	1.782	2.179	2.681	3.055
13	1.350	1.771	2.160	2.650	3.012
14	1.345	1.761	2.145	2.624	2.977
15	1.341	1.753	2.131	2.602	2.947
16	1.337	1.746	2.120	2.583	2.921
17	1.333	1.740	2.110	2.567	2.898
18	1.330	1.734	2.101	2.552	2.878
19	1.328	1.729	2.093	2.539	2.861
20	1.325	1.725	2.086	2.528	2.845
21	1.323	1.721	2.080	2.518	2.831
22	1.321	1.717	2.074	2.508	2.819
23	1.319	1.714	2.069	2.500	2.807
24	1.318	1.711	2.064	2.492	2.797
25	1.316	1.708	2.060	2.485	2.787
26	1.315	1.706	2.056	2.479	2.779
27	1.314	1.703	2.052	2.473	2.771
28	1.313	1.701	2.048	2.467	2.763
29	1.311	1.699	2.045	2.462	2.756
inf.	1.282	1.645	1.960	2.326	2.576

Sumber : Ronald E. Walpole (1995) : Pengantar Statistika.

LAMPIRAN R

HASIL UJI STATISTIK KEKERASAN ODT DOMPERIDONE ANTAR FORMULA

Descriptives

Kekerasan Tablet

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Formula 1	3	2,1167	0,28746	0,16597	1,4026	2,8308	1,89	2,44
Formula 2	3	2,4867	0,14572	0,08413	2,1247	2,8486	2,37	2,65
Formula 3	3	3,0867	0,10066	0,05812	2,8366	3,3367	2,98	3,18
Formula 4	3	2,6900	0,15620	0,09018	2,3020	3,0780	2,59	2,87
Total	12	2,5950	0,39894	0,11516	2,3415	2,8485	1,89	3,18

Test of Homogeneity of Variances

Kekerasan Tablet

Levene Statistic	df1	df2	Sig.
2,085	3	8	0,181

ANOVA

Kekerasan Tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1,474	3	0,491	14,199	0,001
Within Groups	0,277	8	0,035		
Total	1,751	11			

Keterangan:

Ho ditolak jika F_{hitung} (14,199) > F_{tabel} $0,05$ (3,8) (4,07), berarti rata-rata kekerasan tablet dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula.

Multiple Comparisons

Kekerasan Tablet
LSD

(I) Formula	(J) Formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Formula 1	Formula 2	-0,3700*	0,15188	0,041	-0,7202	-0,0198
	Formula 3	-0,9700*	0,15188	0,000	-1,3202	-0,6198
	Formula 4	-0,5733*	0,15188	0,005	-0,9236	-0,2231
Formula 2	Formula 1	0,3700*	0,15188	0,041	0,0198	0,7202
	Formula 3	-0,6000*	0,15188	0,004	-0,9502	-0,2498
	Formula 4	-0,2033	0,15188	0,217	-0,5536	0,1469
Formula 3	Formula 1	0,9700*	0,15188	0,000	0,6198	1,3202
	Formula 2	0,6000*	0,15188	0,004	0,2498	0,9502
	Formula 4	0,3967*	0,15188	0,031	0,0464	0,7469
Formula 4	Formula 1	0,5733*	0,15188	0,005	0,2231	0,9236
	Formula 2	0,2033	0,15188	0,217	-0,1469	0,5536
	Formula 3	-0,39667*	0,15188	0,031	-0,7469	-0,0464

*. The mean difference is significant at the 0,05 level.

Keterangan:

Hasil uji LSD dari keempat formula, diperoleh nilai sig. $< \alpha (0,05)$ sehingga Ho ditolak (*), berarti rata-rata kekerasan tablet dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula yaitu formula 1 menunjukkan perbedaan yang signifikan terhadap formula 2, formula 3, dan formula 4; formula 2 menunjukkan perbedaan yang signifikan terhadap formula 3; dan formula 3 menunjukkan perbedaan yang signifikan terhadap formula 4; hanya formula 2 yang tidak menunjukkan perbedaan yang signifikan terhadap formula 4.

LAMPIRAN S

HASIL UJI STATISTIK KERAPUHAN ODT DOMPERIDONE ANTAR FORMULA

Descriptives

Kerapuhan Tablet

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Formula 1	3	0,9533	0,01528	0,00882	0,9154	0,9913	0,94	0,97
Formula 2	3	1,0033	0,02517	0,01453	0,9408	1,0658	0,98	1,03
Formula 3	3	0,5000	0,00000	0,00000	0,5000	0,5000	0,50	0,50
Formula 4	3	0,9767	0,01155	0,00667	0,9480	1,0054	0,97	0,99
Total	12	0,8583	0,21729	0,06273	0,7203	0,9964	0,50	1,03

Test of Homogeneity of Variances

Kerapuhan Tablet

Levene Statistic	df1	df2	Sig.
2,911	3	8	0,101

ANOVA

Kerapuhan Tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	0,517	3	0,172	689,822	0,000
Within Groups	0,002	8	0,000		
Total	0,519	11			

Keterangan:

Ho diterima jika F_{hitung} (689,822) > F_{tabel} $0,05$ ($3,8$) (4,07), berarti rata-rata kerapuhan tablet dari keempat formula menunjukkan bahwa terdapat perbedaan yang signifikan antar formula.

Multiple Comparisons

Kerapuhan Tablet

LSD

(I) Formula	(J) Formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Formula 1	Formula 2	-0,0500*	0,01291	0,005	-0,0798	-0,0202
	Formula 3	0,4533*	0,01291	0,000	0,4236	0,4831
	Formula 4	-0,0233	0,01291	0,108	-0,0531	0,0064
Formula 2	Formula 1	0,0500*	0,01291	0,005	0,0202	0,0798
	Formula 3	0,5033*	0,01291	0,000	0,4736	0,5331
	Formula 4	0,0266	0,01291	0,073	-0,0031	0,0564
Formula 3	Formula 1	-0,4533*	0,01291	0,000	-0,4831	-0,4236
	Formula 2	-0,5033*	0,01291	0,000	-0,5331	-0,4736
	Formula 4	-0,4766*	0,01291	0,000	-0,5064	-0,4469
Formula 4	Formula 1	0,0233	0,01291	0,108	-0,0064	0,0531
	Formula 2	-0,0266	0,01291	0,073	-0,0564	0,0031
	Formula 3	0,4766*	0,01291	0,000	0,4469	0,5064

*. The mean difference is significant at the 0,05 level.

Keterangan:

Hasil uji LSD dari keempat formula, diperoleh nilai sig. $< \alpha (0,05)$ sehingga Ho ditolak (*), berarti rata-rata kerapuhan tablet dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula yaitu formula 1 menunjukkan perbedaan yang signifikan terhadap formula 2, dan formula 3; formula 2 menunjukkan perbedaan yang signifikan terhadap formula 3; dan formula 3 menunjukkan perbedaan yang signifikan terhadap formula 4; sedangkan formula 1 tidak menunjukkan perbedaan yang signifikan terhadap formula 4; formula 2 tidak menunjukkan perbedaan yang signifikan terhadap formula 4.

LAMPIRAN T

HASIL UJI STATISTIK WAKTU HANCUR ODT DOMPERIDONE ANTAR FORMULA

Descriptives

Waktu Hancur Tablet

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Formula 1	3	35,0667	2,0428	1,1794	29,9919	40,1414	33,60	37,40
Formula 2	3	17,1333	1,1015	0,6359	14,3970	19,8696	16,40	18,40
Formula 3	3	45,3333	0,9237	0,5333	43,0386	47,6281	44,80	46,40
Formula 4	3	27,0000	1,4422	0,8326	23,4173	30,5827	25,40	28,20
Total	12	31,1333	10,9013	3,1469	24,2070	38,0597	16,40	46,40

Test of Homogeneity of Variances

Waktu Hancur Tablet

Levene Statistic	df1	df2	Sig.
1,429	3	8	0,304

ANOVA

Waktu Hancur Tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1290,587	3	430,196	206,825	0,000
Within Groups	16,640	8	2,080		
Total	1307,227	11			

Keterangan:

Ho ditolak jika $F_{\text{hitung}} (206,825) > F_{\text{tabel}, 0,05 (3,8)} (4,07)$, berarti rata-rata waktu hancur dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula.

Multiple Comparisons

Waktu Hancur Tablet
LSD

(I) Formula	(J) Formula	Mean Difference (I-J)	Std, Error	Sig,	95% Confidence Interval	
					Lower Bound	Upper Bound
Formula 1	Formula 2	17,9333*	1,17757	0,000	15,2179	20,6488
	Formula 3	-10,2667*	1,17757	0,000	-12,9821	-7,5512
	Formula 4	8,0667*	1,17757	0,000	5,3512	10,7821
Formula 2	Formula 1	-17,9333*	1,17757	0,000	-20,6488	-15,2179
	Formula 3	-28,2000*	1,17757	0,000	-30,9155	-25,4845
	Formula 4	-9,8666*	1,17757	0,000	-12,5821	-7,1512
Formula 3	Formula 1	10,2667*	1,17757	0,000	7,5512	12,9821
	Formula 2	28,2000*	1,17757	0,000	25,4845	30,9155
	Formula 4	18,3333*	1,17757	0,000	15,6179	21,0488
Formula 4	Formula 1	-8,0666*	1,17757	0,000	-10,7821	-5,3512
	Formula 2	9,8666*	1,17757	0,000	7,1512	12,5821
	Formula 3	-18,3333*	1,17757	0,000	-21,0488	-15,6179

*. The mean difference is significant at the 0,05 level

Keterangan:

Hasil uji LSD dari keempat formula, diperoleh nilai sig. $< \alpha (0,05)$ sehingga Ho ditolak (*), berarti rata-rata waktu hancur tablet dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula, yaitu formula 1 menunjukkan perbedaan yang signifikan terhadap formula 2, formula 3 dan formula 4; formula 2 menunjukkan perbedaan yang signifikan terhadap formula 3 dan formula 4; dan formula 3 menunjukkan perbedaan yang signifikan terhadap formula 4.

LAMPIRAN U
HASIL UJI STATISTIK WAKTU PEMBASAHAAN
ODT DOMPERIDONE ANTAR FORMULA

Descriptives

Waktu Pembasahan Tablet

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Formula 1	3	35,0000	2,09019	1,20677	29,8077	40,1923	33,00	37,17
Formula 2	3	22,4433	2,17222	1,25413	17,0472	27,8394	20,33	24,67
Formula 3	3	44,5567	0,91904	0,53061	42,2736	46,8397	43,50	45,17
Formula 4	3	27,6100	3,08953	1,78374	19,9352	35,2848	24,67	30,83
Total	12	32,4025	8,88730	2,56554	26,7558	38,0492	20,33	45,17

Test of Homogeneity of Variances

Waktu Pembasahan Tablet

Levene Statistic	df1	df2	Sig.
0,776	3	8	0,540

ANOVA

Waktu Pembasahan Tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	829,871	3	276,624	56,810	0,000
Within Groups	38,955	8	4,869		
Total	868,826	11			

Keterangan:

Ho ditolak jika F_{hitung} ($56,810$) > $F_{tabel} 0,05 (3,8)$ ($4,07$), berarti rata-rata waktu hancur tablet dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula.

Multiple Comparisons

Waktu Pembasahan

LSD

(I) Formula	(J) Formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Formula 1	Formula 2	12,55667*	1,80172	0,000	8,4019	16,7115
	Formula 3	-9,55667*	1,80172	0,001	-13,7115	-5,4019
	Formula 4	7,39000*	1,80172	0,003	3,2352	11,5448
Formula 2	Formula 1	-12,5566*	1,80172	0,000	-16,7115	-8,4019
	Formula 3	-22,1133*	1,80172	0,000	-26,2681	-17,9585
	Formula 4	-5,16667*	1,80172	0,021	-9,3215	-1,0119
Formula 3	Formula 1	9,55667*	1,80172	0,001	5,4019	13,7115
	Formula 2	22,11333*	1,80172	0,000	17,9585	26,2681
	Formula 4	16,94667*	1,80172	0,000	12,7919	21,1015
Formula 4	Formula 1	-7,39000*	1,80172	0,003	-11,5448	-3,2352
	Formula 2	5,16667*	1,80172	0,021	1,0119	9,3215
	Formula 3	-16,9466*	1,80172	0,000	-21,1015	-12,7919

*. The mean difference is significant at the 0,05 level.

Keterangan:

Hasil uji LSD dari keempat formula, diperoleh nilai sig. $< \alpha (0,05)$ sehingga Ho ditolak (*), berarti rata-rata waktu pembasahan tablet dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula, yaitu formula 1 menunjukkan perbedaan yang signifikan terhadap formula 2, formula 3 dan formula 4; formula 2 menunjukkan perbedaan yang signifikan terhadap formula 3 dan formula 4; dan formula 3 menunjukkan perbedaan yang signifikan terhadap formula 4.

LAMPIRAN V
HASIL UJI STATISTIK RASIO ABSORPSI AIR
ODT DOMPERIDONE ANTAR FORMULA

Descriptives

Rasio Absorpsi Air Tablet

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Formula 1	3	36,6500	1,13578	0,65574	33,8286	39,4714	35,85	37,95
Formula 2	3	47,0600	3,88918	2,24542	37,3987	56,7213	44,55	51,54
Formula 3	3	39,0967	1,51672	0,87568	35,3289	42,8644	38,08	40,84
Formula 4	3	44,6700	4,75236	2,74377	32,8645	56,4755	41,39	50,12
Total	12	41,8692	5,15002	1,48668	38,5970	45,1413	35,85	51,54

Test of Homogeneity of Variances

Rasio Absorpsi Air Tablet

Levene Statistic	df1	df2	Sig.
4,448	3	8	0,041

ANOVA

Rasio Absorpsi Air Tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	209,148	3	69,716	6,752	0,014
Within Groups	82,602	8	10,325		
Total	291,750	11			

Keterangan:

Ho ditolak jika F_{hitung} (6,752) > F_{tabel} 0,05 (3,8) (4,07), berarti rata-rata waktu hancur tablet dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula.

Multiple Comparisons

Rasio Absorpsi Air Tablet
LSD

(I) Formula	(J) Formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Formula 1	Formula 2	-10,41000*	2,62364	0,004	-16,4601	-4,3599
	Formula 3	-2,44667	2,62364	0,378	-8,4968	3,6035
	Formula 4	-8,02000*	2,62364	0,016	-14,0701	-1,9699
Formula 2	Formula 1	10,41000*	2,62364	0,004	4,3599	16,4601
	Formula 3	7,96333*	2,62364	0,016	1,9132	14,0135
	Formula 4	2,39000	2,62364	0,389	-3,6601	8,4401
Formula 3	Formula 1	2,44667	2,62364	0,378	-3,6035	8,4968
	Formula 2	-7,96333*	2,62364	0,016	-14,0135	-1,9132
	Formula 4	-5,57333	2,62364	0,066	-11,6235	0,4768
Formula 4	Formula 1	8,02000*	2,62364	0,016	1,9699	14,0701
	Formula 2	-2,39000	2,62364	0,389	-8,4401	3,6601
	Formula 3	5,57333	2,62364	0,066	-0,4768	11,6235

*. The mean difference is significant at the 0,05 level.

Keterangan:

Hasil uji LSD dari keempat formula, diperoleh nilai sig. $< \alpha (0,05)$ sehingga Ho ditolak (*), berarti rata-rata rasio absorpsi air tablet dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula, yaitu formula 1 menunjukkan perbedaan yang signifikan terhadap formula 2 dan formula 4; formula 2 menunjukkan perbedaan yang signifikan terhadap formula 3, sedangkan formula 1 tidak menunjukkan perbedaan yang signifikan terhadap formula 3; formula 2 juga tidak menunjukkan perbedaan yang signifikan terhadap formula 4; dan formula 3 juga tidak menunjukkan perbedaan yang signifikan terhadap formula 4.

LAMPIRAN W

HASIL UJI STATISTIK PENETAPAN KADAR ODT DOMPERIDONE ANTAR FORMULA

Descriptives

Penetapan Kadar Tablet

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max	
					Lower Bound	Upper Bound			
17 5	Formula 1	3	103,1967	2,00742	1,15898	98,2100	108,1834	100,93	104,75
	Formula 2	3	99,8900	0,82456	0,47606	97,8417	101,9383	99,36	100,84
	Formula 3	3	99,4100	1,78670	1,03155	94,9716	103,8484	97,58	101,15
	Formula 4	3	99,9133	1,58926	0,91756	95,9654	103,8613	98,08	100,90
	Pembanding 1	3	96,4967	1,78802	1,03232	92,0550	100,9384	94,50	97,95
	Pembanding 2	3	103,0467	2,62681	1,51659	96,5213	109,5720	101,24	106,06
	Total	18	100,3256	2,82393	0,66561	98,9212	101,7299	94,50	106,06

Test of Homogeneity of Variances

Penetapan Kadar Tablet

Levene Statistic	df1	df2	Sig.
1,089	5	12	0,415

ANOVA

Penetapan Kadar Tablet

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	94,518	5	18,904	5,526	0,007
Within Groups	41,050	12	3,421		
Total	135,568	17			

Keterangan:

Ho ditolak jika $F_{hitung} (5,526) > F_{tabel, 0,05 (5,12)} (3,11)$, berarti rata-rata kadar domperidone dalam tablet dari keempat formula dan tablet pembanding menunjukkan bahwa ada perbedaan yang signifikan antar formula.

Penetapan Kadar Tablet
LSD

Multiple Comparisons

17
7

(I) Formula	(J) Formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Formula 1	Formula 2	3,30667*	1,51014	0,049	0,0163	6,5970
	Formula 3	3,78667*	1,51014	0,028	0,4963	7,0770
	Formula 4	3,28333	1,51014	0,050	-0,0070	6,5737
	Pembanding 1	6,70000*	1,51014	0,001	3,4097	9,9903
	Pembanding 2	0,15000	1,51014	0,923	-3,1403	3,4403
Formula 2	Formula 1	-3,30667*	1,51014	0,049	-6,5970	-0,0163
	Formula 3	0,48000	1,51014	0,756	-2,8103	3,7703
	Formula 4	-0,02333	1,51014	0,988	-3,3137	3,2670
	Pembanding 1	3,39333*	1,51014	0,044	0,1030	6,6837
	Pembanding 2	-3,15667	1,51014	0,059	-6,4470	0,1337
Formula 3	Formula 1	-3,78667*	1,51014	0,028	-7,0770	-0,4963
	Formula 2	-0,48000	1,51014	0,756	-3,7703	2,8103
	Formula 4	-0,50333	1,51014	0,745	-3,7937	2,7870
	Pembanding 1	2,91333	1,51014	0,078	-0,3770	6,2037
	Pembanding 2	-3,63667*	1,51014	0,033	-6,9270	-0,3463
Formula 4	Formula 1	-3,28333	1,51014	0,050	-6,5737	0,0070
	Formula 2	0,02333	1,51014	0,988	-3,2670	3,3137
	Formula 3	0,50333	1,51014	0,745	-2,7870	3,7937
	Pembanding 1	3,41667*	1,51014	0,043	0,1263	6,7070
	Pembanding 2	-3,13333	1,51014	0,060	-6,4237	0,1570

(I) Formula	(J) Formula	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Pembanding 1	Formula 1	-6,70000*	1,51014	0,001	-9,9903	-3,4097
	Formula 2	-3,39333*	1,51014	0,044	-6,6837	-0,1030
	Formula 3	-2,91333	1,51014	0,078	-6,2037	0,3770
	Formula 4	-3,41667*	1,51014	0,043	-6,7070	-0,1263
	Pembanding 2	-6,55000*	1,51014	0,001	-9,8403	-3,2597
Pembanding 2	Formula 1	-0,15000	1,51014	0,923	-3,4403	3,1403
	Formula 2	3,15667	1,51014	0,059	-0,1337	6,4470
	Formula 3	3,63667*	1,51014	0,033	0,3463	6,9270
	Formula 4	3,13333	1,51014	0,060	-0,1570	6,4237
	Pembanding 1	6,55000*	1,51014	0,001	3,2597	9,8403

*. The mean difference is significant at the 0,05 level.

Keterangan:

Hasil uji LSD dari keempat formula, diperoleh nilai $\text{sig.} < \alpha (0,05)$ sehingga H_0 ditolak (*), berarti rata-rata penetapan kadar dari keempat formula menunjukkan bahwa ada perbedaan yang signifikan antar formula yaitu formula 1 menunjukkan perbedaan yang signifikan terhadap formula 2, formula 3 dan pembanding 1; formula 2 menunjukkan perbedaan yang signifikan terhadap pembanding 1; formula 3 menunjukkan perbedaan yang signifikan terhadap pembanding 2; dan formula 4 menunjukkan perbedaan yang signifikan terhadap pembanding 1, sedangkan formula 1 yang tidak menunjukkan perbedaan yang signifikan terhadap formula 4 dan pembanding 2; formula 2 juga tidak menunjukkan perbedaan yang signifikan terhadap formula 3, formula 4, dan pembanding 2; formula 3 juga tidak menunjukkan perbedaan yang signifikan terhadap formula 4 dan pembanding 1; serta formula 4 juga tidak menunjukkan perbedaan yang signifikan terhadap pembanding 2

LAMPIRAN X

HASIL UJI STATISTIK PERSEN OBAT TERLEPAS TABLET DOMPERIDONE PADA t= 30 MENIT

Descriptives

Persen Obat Terlepas

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Formula 1	3	89,536	8,2042	4,7367	69,156	109,917	80,2	95,9
Formula 2	3	92,546	2,8620	1,6524	85,436	99,656	90,0	95,6
Formula 3	3	93,130	1,6314	0,9419	89,077	97,182	91,8	94,9
Formula 4	3	91,643	2,0430	1,1795	86,568	96,718	90,2	93,9
Pembanding 1	3	96,066	1,3448	0,7764	92,726	99,407	94,5	96,9
Pembanding 2	3	93,233	0,5116	0,2953	91,962	94,504	92,7	93,7
Total	18	92,692	3,7390	0,8813	90,833	94,552	80,2	96,9

Test of Homogeneity of Variances

Persen ObatTerlepas

Levene Statistic	df1	df2	Sig.
6,027	5	12	0,005

ANOVA

Persen Obat Terlepas

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	68,851	5	13,770	0,979	0,469
Within Groups	168,814	12	14,068		
Total	237,665	17			

Keterangan:

Ho diterima jika F_{hitung} (0,979) < F_{tabel} 0,05 (5,12) (3,11), berarti rata-rata persen obat terlarut pada t = 30 menit dari keempat formula serta tablet pembanding menunjukkan bahwa tidak ada perbedaan yang signifikan antar formula.

LAMPIRAN Y

HASIL UJI STATISTIK PERSEN EFISIENSI DISOLUSI ODT DOMPERIDONE ANTAR FORMULA

Descriptives

Persen Efisiensi Disolusi Tablet

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Formula 1	3	89,9800	7,4843	4,3211	71,387	108,572	81,4	95,2
Formula 2	3	93,2767	1,4756	0,8519	89,611	96,942	91,6	94,4
Formula 3	3	93,3767	1,7333	1,0007	89,070	97,682	92,1	95,3
Formula 4	3	93,2467	1,7130	0,9890	88,991	97,502	91,7	95,1
Pembanding 1	3	91,4467	2,1158	1,2216	86,190	96,702	90,0	93,8
Pembanding 2	3	92,6367	0,7715	0,4454	90,720	94,553	91,7	93,3
Total	18	92,3272	3,1257	0,7367	90,772	93,881	81,4	95,3

Test of Homogeneity of Variances

Persen Efisiensi Disolusi Tablet

Levene Statistic	df1	df2	Sig.
6,955	5	12	0,003

ANOVA

Persen Efisiensi Disolusi

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	27,686	5	5,537	0,480	0,785
Within Groups	138,410	12	11,534		
Total	166,096	17			

Keterangan:

Ho diterima jika $F_{hitung} (0,480) < F_{tabel} 0,05 (5,12) (3,11)$, berarti rata-rata waktu hancur tablet dari keempat formula dan tablet pembanding menunjukkan bahwa tidak ada perbedaan yang signifikan antar formula.

LAMPIRAN Z

UJI F KURVA BAKU DENGAN HCl 0,1N UNTUK UJI PENETAPAN KADAR ODT DOMPERIDONE

Rep.	Konsentrasi (ppm) (x)	Absorbansi (y)	x ²	y ²	xy
I	2,012	0,097	4,0481	0,0094	0,1952
	4,024	0,140	16,1926	0,0196	0,5634
	6,036	0,203	36,4333	0,0412	1,2253
	8,048	0,253	64,7703	0,0640	2,0361
	10,06	0,313	101,2036	0,0980	3,1488
	12,072	0,372	145,7332	0,1384	4,4908
	14,084	0,420	198,3591	0,1764	5,9153
Σ		56,336	1,798	566,74016	0,54698
					17,57482

Persamaan Regresi pada replikasi I → $y = 0,0274x + 0,0364$
 $r_{hitung}/r_{tabel}: 0,9993/0,754$

Rep.	Konsentrasi (ppm) (x)	Absorbansi (y)	x ²	y ²	xy
II	2,012	0,090	4,0481	0,0081	0,1811
	4,024	0,145	16,1926	0,0210	0,5835
	6,036	0,195	36,4333	0,0380	1,1770
	8,048	0,260	64,7703	0,0676	2,0925
	10,06	0,319	101,2036	0,1018	3,2091
	12,072	0,371	145,7332	0,1376	4,4787
	14,084	0,430	198,3591	0,1849	6,0561
Σ		56,336	1,81	566,74016	0,559052
					17,778032

Persamaan Regresi pada replikasi II → $y = 0,0283x + 0,0306$
 $r_{hitung}/r_{tabel}: 0,9996/0,754$

Rep.	Konsentrasi (ppm) (x)	Absorbansi (y)	x^2	y^2	xy
III	2,008	0,089	4,0321	0,0079	0,1787
	4,016	0,139	16,1283	0,0193	0,5582
	6,024	0,210	36,2886	0,0441	1,2650
	8,032	0,264	64,5130	0,0697	2,1204
	10,04	0,326	100,8016	0,1063	3,2730
	12,048	0,373	145,1543	0,1391	4,4939
	14,056	0,426	197,5711	0,1815	5,9879
Σ	56,224	1,827	564,48896	0,567919	17,877224

Persamaan Regresi pada replikasi III → $y = 0,0284x + 0,0331$
 $r_{hitung}/r_{tabel}: 0,9988/0,754$

	$\sum x^2$	$\sum xy$	$\sum y^2$	n	Residual SS	RDF
Persamaan regresi 1	566,7401	17,5748	0,5469	7	0,0019783	5
Persamaan regresi 2	566,7401	17,7780	0,5590	7	0,0013741	5
Persamaan regresi 3	564,4889	17,8772	0,5679	7	0,0017517	5
<i>Pooled regression</i>				21	0,0051043	15
<i>Common regression</i>	1697,9692	53,3145	1,67902		0,0052276	15

$$F_{hitung} = 0,0906$$

$$F_{tabel\ 0,05\ (4,15)} = 3,06$$

$F_{hitung} = 0,0906 < F_{tabel\ 0,05\ (3,12)} = 3,06$; yang berarti tidak ada perbedaan bermakna antar replikasi pada pembuatan kurva baku untuk uji penetapan kadar ODT domperidone.

LAMPIRAN AA

HASIL UJI STATISTIK HASIL PERCOBAAN DAN HASIL STABILITAS PADA UJI WAKTU HANCUR ODT DOMPERIDONE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Waktu_Hancur	31,1325	4	11,97526	5,98763
	Waktu_Hancur_setelah_uji_stabilitas	26,1650	4	13,63814	6,81907

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Waktu_Hancur & Waktu_Hancur_setelah_uji_stabilitas	4	0,981	0,019

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)			
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference							
				Lower	Upper						
Pair 1	Waktu_Hancur - Waktu_Hancur_setelah_uji_stabilitas	4,967	2,992	1,496	0,2054	9,7295	3,32	3	0,045		

Hipotesa Pengujian :

Ho ditolak jika $T_{hitung} (3,320) > T_{0,025 (3)} (3,182)$, berarti hasil percobaan dan hasil stabilitas pada uji waktu hancur berbeda bermakna antar formula

LAMPIRAN AB

HASIL UJI STATISTIK HASIL PERCOBAAN DAN HASIL STABILITAS PADA UJI WAKTU PAMBASAHAAN ODT DOMPERIDONE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Waktu Pembasahan	32,4025	4	9,60506	4,80253
	Waktu Pembasahan setelah uji stabilitas	28,3325	4	11,78305	5,89153

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Waktu_pembasahan & Waktu_pembasahan_setelah_uji_stabilitas	4	0,997	0,003

Paired Samples Test

	Paired Differences						t	df	Sig. (2-tailed)			
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference								
				Lower	Upper							
Pair 1	Waktu_pem basahan-Waktu_pem basahan_set elah_uji_sta bilitas	4,070	2,33654	1,168	0,3520	7,7879	3,484	3	0,04			

Hipotesa Pengujian :

Ho ditolak jika $T_{hitung} (3,484) > T_{0,025(3)} (3,182)$, berarti hasil percobaan dan hasil stabilitas pada uji waktu pembashan berbeda bermakna antar fomula

LAMPIRAN AC

HASIL UJI ANAVA KEKERASAN ODT DOMPERIDONE DENGAN *DESIGN EXPERT*

Use your mouse to right click on individual cells for definitions.

Response **1** **Kekerasan**

ANOVA for selected factorial model

Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prop > F
Model	1.47	3	0.49	14.20	0.0014
A Kons.	5.333E-004	1	5.333E-004	0.015	0.9043
Crosppovidone					significant
B- Kons.	1.03	1	1.03	29.84	0.0006
PVP K-30					
AB	0.44	1	0.44	12.74	0.0073
Pure Error	0.28	8	0.035		
Cor Total	1.75	11			

The Model F-value of 14.20 implies the model is significant. There is only a 0.14% chance that a "Model F-Value" this large could occur due to noise. Values of "Prob > F" less than 0.0500 indicate model terms are significant. In this case B, AB are significant model terms. Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	0.19	R-Squared	0.8419
Mean	2.60	Adj R-Squared	0.7826
C.V. %	7.17	Pred R-Squared	0.6443
PRESS	0.62	Adeq Precision	9.032

The "Pred R-Squared" of 0.6443 is in reasonable agreement with the "Adj R- Squared" of 0.7826.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4

is desirable. Your ratio of 9.032 indicates an adequate signal. This model can be used to navigate the design space.

Factor	Coefficient	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	Estimate	1	0.054	2.47	2.72	
A- Kons.	2.60	1	0.054	-0.13	0.12	1.00
Crospovidone						
B-. KonsPVP K-30	-6.667E-003	1	0.054	0.17	0.42	1.00
AB	0.29	1	0.054	-0.32	-0.068	1.00

Final Equation in Terms of Coded Factors:

$$\begin{aligned}
 \text{Kekerasan} &= \\
 +2.60 & \\
 -6.667E-003 & * A \\
 +0.29 & * B \\
 -0.19 & * A * B
 \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned}
 \text{Kekerasan} &= \\
 +2.59500 & \\
 -6.66667E-003 & * Crospovidone \\
 +0.29333 & * PVP K-30 \\
 -0.19167 & * Crospovidone * PVP K-30
 \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node. In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
- 2) Studentized residuals versus predicted values to check for constant error.
- 3) Externally Studentized Residuals to look for outliers, i.e., influential values.
- 4) Box-Cox plot for power transformations.

If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.

LAMPIRAN AD

HASIL UJI ANAVA KERAPUHAN ODT DOMPERIDONE DENGAN DESIGN EXPERT

Response 2 Kerapuhan

ANOVA for selected factorial model

Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value	Prop > F
Model	1.30	3	0.43	1625.36	< 0.0001	significant
A Kons.	1.875E-003	1	1.875E-003	7.03	0.0292	
Crospovidone	0.69	1	0.69	2574.03	< 0.0001	
B- Kons.	0.61	1	0.61	2295.03	< 0.0001	
PVP K-30	2.133E-003	8	2.667E-004			
AB	Cor Total	11				

The "Model F-value" of 1625.36 implies the model is significant. There is only implies the model is not significant relative to the noise. There is a 46.98 % chance that a "Model F-value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant. In this case there are no significant model terms. Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	0.016	R-Squared	0.9984
Mean	0.98	Adj R-Squared	0.9977
C.V. %	1.67	Pred R-Squared	0.9963
PRESS	4.800E-003	Adeq Precision	98.641

A negative "Pred R-Squared" implies that the overall mean is a better predictor of your response than the current model.

"Adeq Precision" measures the signal to noise ratio. A ratio of 2.07 indicates an inadequate signal and we should not use this model to navigate the design space.

Factor	Coefficient	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	0.98	1	4.714E-003	0.97	0.99	
A- Kons. Crospovidone	0.012	1	4.714E-003	1.629E-003	0.023	1.00
B- Kons. PVP K-30	-0.24	1	4.714E-003	-0.25	-0.23	1.00
AB	0.23	1	4.714E-003	0.21	0.24	1.00

Final Equation in Terms of Coded Factors:

$$\begin{aligned}
 \text{Kerapuhan} &= \\
 +0.98 & \\
 -0.012 & * A \\
 -0.24 & * B \\
 +0.23 & * A * B
 \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned}
 \text{Kerapuhan} &= \\
 +0.97750 & \\
 -0.012500 & * \text{Crospovidone} \\
 -0.23917 & * \text{PVP K-30} \\
 +0.22583 & * \text{Crospovidone} * \text{PVP K-30}
 \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node. In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
 - 2) Studentized residuals versus predicted values to check for constant error.
 - 3) Externally Studentized Residuals to look for outliers, i.e., influential values.
 - 4) Box-Cox plot for power transformations.
- If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.

LAMPIRAN AE

HASIL UJI ANAVA WAKTU HANCUR ODT DOMPERIDONE DENGAN DESIGN EXPERT

Use your mouse to right click on individual cells for definitions.

Response **3** **Waktu hancur**

ANOVA for selected factorial model

Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value	Prop > F
Model	1290.59	3	430.20	206.82	< 0.0001	significant
A Kons.	986.45	1	986.45	474.26	< 0.0001	
Crospovidone						
B- Kons.	304.01	1	304.01	146.16	< 0.0001	
PVP K-30						
AB	0.12	1	0.12	0.058	0.8162	
Pure Error	16.64	8	2.08			
Cor Total	1307.23	11				

The Model F-value of 206.82 implies the model is significant. There is only a 0.01% chance that a "Model F-Value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant. In this case A, B, are significant model terms.

Values greater than 0.1000 indicate the model terms are not significant.

If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	1.44	R-Squared	0.9873
Mean	31.13	Adj R-Squared	0.9825
C.V. %	4.63	Pred R-Squared	0.9714
PRESS	37.44	Adeq Precision	33.867

The "Pred R-Squared" of 0.9714 is in reasonable agreement with the "Adj R-Squared" of 0.9825.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4

is desirable. Your ratio of 33.867 indicates an adequate signal. This model can be used to navigate the design space.

Factor	Coefficient	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	31.13	1	0.42	30.17	32.09	
A- Kons.	-9.07	1	0.42	-10.03	-8.11	1.00
Crospovidone						
B- Kons. PVP	5.03	1	0.42	4.07	5.99	1.00
K-30						
AB	-0.100	1	0.42	-1.06	0.86	1.00

Final Equation in Terms of Coded Factors:

$$\begin{aligned}
 \text{Waktu Hancur} &= \\
 +31.13 & \\
 -9.07 & * A \\
 +5.03 & * B \\
 -0.100 & * A * B
 \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned}
 \text{Waktu Hancur} &= \\
 +31.13333 & \\
 -9.06667 & * \text{Crospovidone} \\
 +5.03333 & * \text{PVP K-30} \\
 -0.100000 & * \text{Crospovidone} * \text{PVP K-30}
 \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node. In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
 - 2) Studentized residuals versus predicted values to check for constant error.
 - 3) Externally Studentized Residuals to look for outliers, i.e., influential values.
 - 4) Box-Cox plot for power transformations.
- If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.

LAMPIRAN AF
HASIL UJI ANAVA WAKTU PEMBASAHAAN ODT
DOMPERIDONE DENGAN DESIGN EXPERT

Response 4 **Waktu Pembasahan**

ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value	Prop > F
Model	829.87	3	276.62	56.81	< 0.0001	significant
A Kons.	652.84	1	652.84	134.07	< 0.0001	
Crospovidone						
B- Kons.	162.58	1	162.58	33.39	0.0004	
PVP K-30						
AB	14.45	1	14.45	2.97	0.1232	
Pure Error	38.95	8	4.87			
Cor Total	868.83	11				

The Model F-value of 56.81 implies the model is significant. There is only a 0.01% chance that a "Model F-Value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant. In this case A, B are significant model terms.

Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	2.21	R-Squared	0.9552
Mean	32.40	Adj R-Squared	0.9384
C.V. %	6.81	Pred R-Squared	0.8991
PRESS	87.65	Adeq Precision	17.357

The "Pred R-Squared" of 0.8991 is in reasonable agreement with the "Adj R-Squared" of 0.9384.

"Adeq Precision" measures the signal to noise ratio. A ratio greater than 4 is desirable. Your ratio of 17.357 indicates an adequate signal. This model can be used to navigate the design space.

Factor	Coefficient	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	32.40	1	0.64	30.93	33.87	
A- Kons.	-7.38	1	0.64	-8.84	-5.91	1.00
Crospovidone						
B- Kons. PVP	3.68	1	0.64	2.21	5.15	1.00
K-30						
AB	-1.10	1	0.64	-2.57	0.37	1.00

Final Equation in Terms of Coded Factors:

$$\begin{aligned} \text{Waktu Pembasahan} &= \\ +32.40 & \\ -7.38 & * A \\ +3.68 & * B \\ -1.10 & * A * B \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned} \text{Waktu Pembasahan} &= \\ +32.40250 & \\ -7.37583 & * \text{Crospovidone} \\ +3.68083 & * \text{PVP K-30} \\ -1.09750 & * \text{Crospovidone} * \text{PVP K-30} \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node. In the Diagnostics Node, Select Case Statistics from the View Menu. Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
- 2) Studentized residuals versus predicted values to check for constant error.
- 3) Externally Studentized Residuals to look for outliers, i.e., influential values.
- 4) Box-Cox plot for power transformations.

If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.

LAMPIRAN AG

HASIL UJI ANAVA RASIO ABSORPSI AIR ODT DOMPERIDONE DENGAN DESIGN EXPERT

Response 5 Rasio Absorpsi Air

ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value Prop > F	
Model	198.37	3	66.12	3.66	0.0631	not significant
A Kons.	189.13	1	189.13	10.47	0.0120	
Crospovidone						
B- Kons.	6.16	1	6.16	0.34	0.5752	
PVP K-30						
AB	3.08	1	3.08	0.17	0.6905	
Pure Error	144.52	8	18.06			
Cor Total	342.89	11				

The Model F-value of 3.66 implies there is a 6.31% chance that a "Model F-Value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant.

In this case A are significant model terms.

Values greater than 0.1000 indicate the model terms are not significant.

If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

Std. Dev.	3.21	R-Squared	0.7169
Mean	41.87	Adj R-Squared	0.6107
C.V. %	7.67	Pred R-Squared	0.3630
PRESS	185.85	Adeq Precision	5.611

The "Pred R-Squared" of 0.0517 is not as close to the "Adj R-Squared" of 0.4205 as one might normally expect. This may indicate a large block effect or a possible problem with your model and/or data. Things to consider are model reduction, response transformation, outliers, etc. "Adeq Precision" measures the signal to noise ratio. A ratio of 3.82

indicates an inadequate signal and we should not use this model to navigate the design space.

Factor	Coefficient	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	41.84	1	1.23	39.01	44.67	41.84
A- Kons.	3.97	1	1.23	1.14	6.80	3.97
Crospovidone						
B- Kons. PVP	0.72	1	1.23	-2.11	3.55	0.72
K-30						
AB	-0.51	1	1.23	-3.34	2.32	-0.51

Final Equation in Terms of Coded Factors:

$$\begin{aligned}
 \text{Rasio Absorpsi Air} &= \\
 +41.84 & \\
 +3.97 & * A \\
 +0.72 & * B \\
 -0.51 & * A * B
 \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned}
 \text{Rasio Absorpsi Air} &= \\
 +41.84333 & \\
 +3.97000 & * \text{Crospovidone} \\
 +0.71667 & * \text{PVP K-30} \\
 -0.50667 & * \text{Crospovidone} * \text{PVP K-30}
 \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node. In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
- 2) Studentized residuals versus predicted values to check for constant error.
- 3) Externally Studentized Residuals to look for outliers, i.e., influential values.
- 4) Box-Cox plot for power transformations.

If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.

LAMPIRAN AH

HASIL UJI ANAVA PERSEN EFISIENSI DISOLUSI ODT DOMPERIDONE DENGAN DESIGN EXPERT

Response 6 %ED
ANOVA for selected factorial model
Analysis of variance table [Partial sum of squares - Type III]

Source	Sum of Squares	df	Mean Square	F Value	p-value	Prop > F
Model	24.83	3	8.28	0.52	0.6826	not significant
A Kons.	7.52	1	7.52	0.47	0.5128	
Crospovidone						
B- Kons.	8.50	1	8.50	0.53	0.4873	
PVP K-30						
AB	8.81	1	8.81	0.55	0.4798	
Pure Error	128.27	8	16.03			
Cor Total	153.09	11				

The "Model F-value" of 0.52 implies the model is not significant relative to the noise. There is a 68.26 % chance that a "Model F-value" this large could occur due to noise.

Values of "Prob > F" less than 0.0500 indicate model terms are significant. In this case there are no significant model terms.

Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model. Model reduction may improve your model.

Std. Dev.	4.00	R-Squared	0.1622
Mean	92.47	Adj R-Squared	-0.1520
C.V. %	4.33	Pred R-Squared	-0.8851
PRESS	288.60	Adeq Precision	1.469

A negative "Pred R-Squared" implies that the overall mean is a better predictor of your response than the current model.

"Adeq Precision" measures the signal to noise ratio. A ratio of 1.47

indicates an inadequate signal and we should not use this model to navigate the design space.

Factor	Coefficient	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	92.47	1	1.16	89.80	95.14	
A- Kons.	0.79	1	1.16	-1.87	3.46	1.00
Crospovidone						
B- Kons. PVP	0.84	1	1.16	-1.82	3.51	1.00
K-30						
AB	-0.86	1	1.16	-3.52	1.81	1.00

Final Equation in Terms of Coded Factors:

$$\begin{aligned} \%ED &= \\ +92.47 & \\ +0.79 & * A \\ +0.84 & * B \\ -0.86 & * A * B \end{aligned}$$

Final Equation in Terms of Actual Factors:

$$\begin{aligned} \%ED &= \\ +92.47000 & \\ +0.79167 & * Crospovidone \\ +0.84167 & * PVP K-30 \\ -0.85667 & * Crospovidone * PVP K-30 \end{aligned}$$

The Diagnostics Case Statistics Report has been moved to the Diagnostics Node. In the Diagnostics Node, Select Case Statistics from the View Menu.

Proceed to Diagnostic Plots (the next icon in progression). Be sure to look at the:

- 1) Normal probability plot of the studentized residuals to check for normality of residuals.
- 2) Studentized residuals versus predicted values to check for constant error.
- 3) Externally Studentized Residuals to look for outliers, i.e., influential values.
- 4) Box-Cox plot for power transformations.

If all the model statistics and diagnostic plots are OK, finish up with the Model Graphs icon.

LAMPIRAN AI

HASIL UJI STATISTIK HASIL PERCOBAAN DAN HASIL TEORITIS PADA UJI KEKERASAN ODT DOMPERIDONE

Paired Samples Statistics

		Mean	N	Std, Deviation	Std, Error Mean
Pair 1	Hasil Percobaan pada Uji Kekerasan	2,5975	4	0,40442	0,20221
	Hasil Percobaan pada Uji Kekerasan	2,6000	4	0,40035	0,20018

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Hasil Percobaan pada Uji Kekerasan & Hasil Teoritis pada Uji Kekerasan	4	1,000	0,000

Paired Samples Test

	Paired Differences					t	d f	Sig. (2-tailed)			
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference							
				Lower	Upper						
Pai Hasil r 1 Percobaan pada Uji Kekerasan - Hasil Teoritis pada Uji Kekerasan	-0,002	0,0062	0,0031	-0,0124	0,0074	-0,797	3	0,48			

Hipotesa Pengujian :

Ho diterima jika $T_{hitung} (-0,797) < T_{0,025(3)} (3,182)$, berarti hasil percobaan dan hasil teoritis pada uji kekerasan tidak berbeda bermakna antar formula,

LAMPIRAN AJ

HASIL UJI STATISTIK HASIL PERCOBAAN DAN HASIL TEORITIS PADA UJI KERAPUHAN ODT DOMPERIDONE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Hasil Percobaan pada Uji Kerapuhan	1,1700	4	0,73016	0,36508
	Hasil Teoritis pada Uji Kerapuhan	1,1700	4	0,73248	0,36624

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Hasil Percobaan pada Uji Kerapuhan & Hasil Teoritis pada Uji Kerapuhan	4	1,000	0,000

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)			
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference							
				Lower	Upper						
Pai r 1	Hasil Percobaan pada Uji Kerapuhan - Hasil Teoritis pada Uji Kerapuhan	0,000	0,0081	0,0040	-0,0129	0,0129	0,000	3	1,000		

Hipotesa Pengujian :

Ho diterima jika $T_{hitung} (0,000) < T_{0,025 (3)} (3,182)$, berarti hasil percobaan dan hasil teoritis pada uji kerapuhan tidak berbeda bermakna antar formula,

LAMPIRAN AK

HASIL UJI STATISTIK HASIL PERCOBAAN DAN HASIL TEORITIS PADA UJI WAKTU HANCUR ODT DOMPERIDONE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Hasil Percobaan pada Uji Waktu Hancur	28,5825	4	11,94328	5,97164
	Hasil Teoritis pada Uji Waktu Hancur	28,5800	4	11,94372	5,97186

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1 Hasil Percobaan pada Uji Waktu Hancur & Hasil Teoritis pada Uji Waktu Hancur		4	1,000	0,000

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)			
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference							
				Lower	Upper						
Pai r 1 Hasil Percobaan pada Uji Waktu Hancur - Hasil Teoritis pada Uji Waktu Hancur	0,0025	0,0050	0,0025	-0,005	0,0104	1,000	3	0,391			

Hipotesa Pengujian :

Ho diterima jika $T_{hitung} (1,000) < T_{0,025 (3)} (3,182)$, berarti hasil percobaan dan hasil teoritis pada uji waktu hancur tidak berbeda bermakna antar formula,

LAMPIRAN AL

HASIL UJI STATISTIK HASIL PERCOBAAN DAN HASIL TEORITIS PADA UJI WAKTU PEMBASAHAAN ODT DOMPERIDONE

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
Pair 1 Hasil Percobaan pada Uji WaktuPembasahan	29,5800	4	6,84209	3,42105
Hasil Teoritis pada Uji Waktu Pembasahan	29,5200	4	6,71183	3,35592

Paired Samples Correlations

	N	Correlation	Sig.
Pair 1 Hasil Percobaan pada Uji WaktuPembasahan & Hasil Teoritis pada Uji Waktu Pembasahan	4	1,000	0,000

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)			
	Mea n	Std. Deviat ion	Std. Error Mea n	95% Confidence Interval of the Difference							
				Lower	Upper						
Pair 1 Hasil Percobaan pada Uji WaktuPembasahan - Hasil Teoritis pada Uji Waktu Pembasahan	0,060	0,2060	0,103	-0,267	0,3879	0,582	33	0,601			

Hipotesa Pengujian :

Ho diterima jika $T_{hitung} (0,582) < T_{0,025 (3)} (3,182)$, berarti hasil percobaan dan hasil teoritis pada uji waktu pembasahan tidak berbeda bermakna antar formula.

LAMPIRAN AM

HASIL UJI STATISTIK HASIL PERCOBAAN DAN HASIL TEORITIS PADA UJI RASIO ABSORPSI AIR ODT DOMPERIDONE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Hasil Percobaan pada Uji Rasio Absorpsi Air	41,7450	4	5,00350	2,50175
	Hasil Teoritis pada Uji Rasio Absorpsi Air	41,8400	4	4,69601	2,34801

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Hasil Percobaan pada Uji Rasio Absorpsi Air & Hasil Teoritis pada Uji Rasio Absorpsi Air	4	0,973	0,027

Paired Samples Test

	Paired Differences					t	df	Sig, (2-tailed)			
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference							
				Lower	Upper						
Pair Hasil Percobaan 1 pada Uji Rasio Absorpsi Air - Hasil Teoritis pada Uji Rasio Absorpsi Air	-0,095	1,1773	0,5886	-1,9683	1,7783	-0,161	3	0,88			

Hipotesa Pengujian :

Ho diterima jika $T_{hitung} (-0,161) < T_{0,025 (3)} (3,182)$, berarti hasil percobaandan hasil teoritis pada uji rasio absorpsi air tidak berbeda bermakna antar fomula.

LAMPIRAN AN
HASIL UJI STATISTIK HASIL PERCOBAAN DAN HASIL
TEORITIS PADA PERSEN EFISIENSI DISOLUSI ODT
DOMPERIDONE

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Hasil Percobaan pada Uji Persen Efisiensi Disolusi	92,4725	4	1,66260	0,83130
	Hasil Teoritis pada Uji Persen Efisiensi Disolusi	92,4700	4	1,66104	0,83052

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Hasil Percobaan pada Uji Persen Efisiensi Disolusi & Hasil Teoritis pada Uji Persen Efisiensi Disolusi	4	1,000	0,000

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)			
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference							
				Lower	Upper						
PairDisolusi - 1 Hasil_Teoritis pada Uji Persen Efisiensi Disolusi	0,002	0,005	0,0025	-0,0054	0,0104	1,00	3	0,391			

Hipotesa Pengujian :

Ho diterima jika $T_{hitung} (1,000) < T_{0,025 (3)} (3,182)$, berarti hasil percobaandan hasil teoritis pada uji persen efisiensi disolusi tidak berbeda bermakna antar fomula.