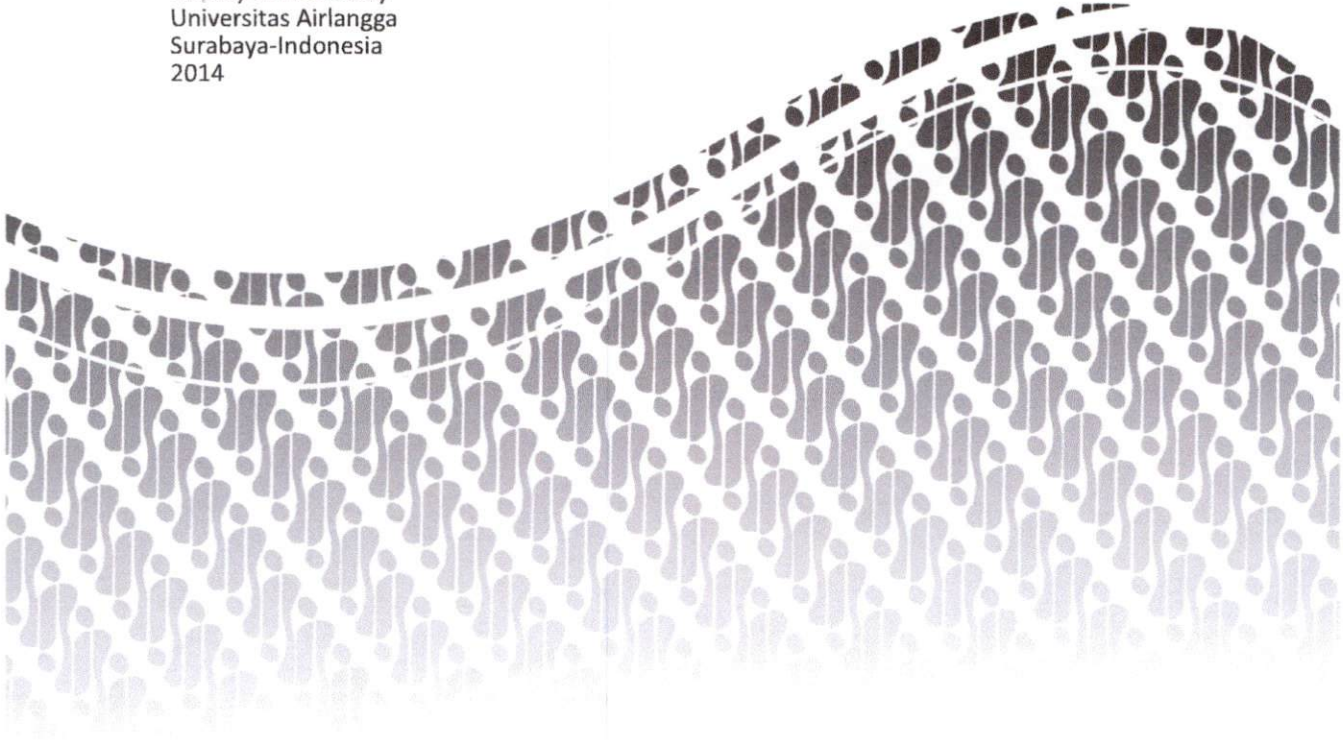
Proceeding

The 1st International Conference on Pharmaceutics & Pharmaceutical Sciences

Published and Organized by
Faculty of Pharmacy
Universitas Airlangga
Surabaya-Indonesia
2014



The 1st International Conference on Pharmaceutics & Pharmaceutical Sciences Proceedings

ISBN : 978-602-72333-0-0
(Letter of National ISBN Agency No. 4127/E.8/p/03.2015 Date 18 March 2015)

1st edition Proceeding
Published by:
Faculty of Pharmacy Universitas Airlangga
Surabaya, Indonesia

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Surabaya 60286
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Website: www.icpps2014.com or www.ff.unair.ac.id
Email: icppinfo@gmail.com

ISBN 978-602-72333-0-0

PREFACE From Chairman

It is our pleasure to present you the proceedings of The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS) organized by The Faculty of Pharmacy Universitas Airlangga Surabaya Indonesia.

The proceeding was produced based on papers and posters presented at The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS), held in Surabaya, Indonesia, 14-15 November 2014.

The proceeding clearly reflects broad interest, from the participants that coming from all around the world.

The papers presented were pharmaceutics and biopharmaceutics; requirements on how to evaluate molecules in discovery and their appropriateness for selection as potential candidate; their development in context of challenges and benefits, together with associated time and cost implications and also requirements to progress through pre-clinical and clinical.

In this an opportunity, I would like to express my appreciation to the editorial team of the proceeding who have been working hard to review manuscripts, and making the first edition of this proceeding be possible.

I would like also to thanks to all invited speakers and presenters who participated in The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS) and your contribution to this proceeding.

Finally, I hope this proceeding will give contribution to the Pharmaceutics and Pharmaceutical Sciences research.

Chairman,

Dra. Esti Hendradi, MSI., Ph.D., Apt

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ICPPS 2014

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CHARACTERIZATION OF PARACETAMOL ORALLY DISINTEGRATING TABLET USING GELATIN 1% AND 2% AS BINDER AND POLYPLASDONE XL-10 10% AS DISINTEGRANT (Prepared by Freeze Drying Method)

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INTRODUCTION

Paracetamol, a para-aminophenol derivative, is usually given per oral as antipyretic and analgesic for the treatment of fever1. Pediatric patients may have difficulty in ingesting conventional tablets because of their underdeveloped muscular and nervous systems2. The concept of Orally Disintegrating Tablets (ODT) emerged with an objective to improve patient's compliance. ODTs disintegrates and dissolves in the mouth in less than 1 minute without the need of water3. Various technologies used in the manufacture of ODT include freeze drying, moulding, direct compression, spray drying, sublimation, and mass extrusion. In the freeze drying method, drying is carried out at low temperature under conditions involving removal of water by sublimation. Here, the drug is physically entrapped in a water soluble matrix, which is then freeze dried to give a product that is highly porous and amorf3. Freeze drying has some disadvantages such as the product obtained has poor mechanical stability and fragile4. Gelatin can inhibit the recrystallization process of amorphous paracetamol by cross-linking and hydrogen bonding between paracetamol and polymer. This interaction may increase the mechanical strength of ODT and keep the amorphous structure5. This study aims to determine the characterization of paracetamol ODT using gelatin as binder (1% and 2%)6, polyplasdone XL-10 as disintegrant (10%)7, and mannitol as filler which prepared by freeze drying method. Paracetamol ODT, physical mixture, and single compound of the material were characterized using Powder X-ray Diffractometry (PXRD), Differential Thermal Analyzer (DTA), and Scanning Electron Microscope (SEM).

MATERIALS AND METHODS

Materials

Paracetamol (Hengshui Jiheng Pharmacy®), Mannitol (Cargill® Cpharm Mannidex 16700), Gelatin (Megasetia®), and Polyplasdone XL-10 (ISP Technologies, Inc.).

Methods

Formulation

There were 3 formulation of paracetamol ODT used in this study, each formula contained 120 mg paracetamol/tablet (Table 1).

Materials	F1	F2	F3
Paracetamol	120 mg	120 mg	120 mg
Mannitol	400 mg	400 mg	400 mg
Gelatin	-	1%	2%
Polyplasdone XL-10	10 %	10%	10 %
Weight*	577,78 mg	584,27 mg	590,91 mg

*The content of gelatin and polyplasdone XL-10 calculated from the total weight of the ODT

Table 12. Formulation of Paracetamol ODT

Preparation of Paracetamol ODT

Mix paracetamol, mannitol and Polyplasdone XL-10 carefully by geometric dillution. Gelatin solution was added to powder mixture until a good suspension obtained. The suspension

were then filled into blister by syringe. The blisters were placed in a deep freezer (-80oC) for 24 hours and then freeze dried (-4oC, 20 Pa) for 24 hours. Tablets obtained were stored at room temperature in a close container.

Characterization of Paracetamol ODT

PXRD (Philips X'pert, Netherland): radiation source Cu-Kα filter Ni and scintillation counter detector. The condition of instrument was about 40kV, 30 mA, and the divergence-scatter slits 0,5o. Scattering intensity used to fixed-time step scanning around 5o-40o.

DTA (Melter Toledo FP 85 TA Cell, US): the experiment were conducted with temperature 50-250oC and heat flow 10oC/minute.

SEM (Jeol-JSM-6360LA, Japan) was performed on the surface and cross section of the tablet with 200x magnification.

RESULTS AND DISCUSSION

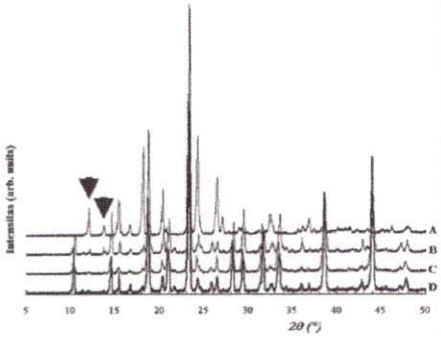

Figure 1. Diffractogram of Paracetamol (A), ODT F1 (B), ODT F2 (C), ODT F3 (D)

Figure 1 showed that single compound of paracetamol showed characteristic crystalline intensity peaks at 12,1o and 13,7o. These peaks showed the alteration of crystallization intensity between paracetamol single compound with paracetamol ODT. The diffractogram showed that F2 has the lowest intensity. However, the decreasing of paracetamol intensity of F2 and F3 was not very significant because of the differences in the amount of gelatin was very small.

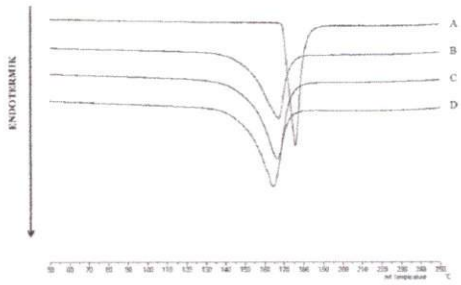

Figure 2. Termogram of Paracetamol (A), ODT F1 (B), ODT F2 (C), ODT F3 (D)

Figure 2 showed the melting point of paracetamol ODTs in each formulation compared to pure paracetamol. The melting point of paracetamol, mannitol, F1, F2, F3 were 171,8oC; 169,6oC; 163,6oC; 162,9oC; 161,2oC. The decreasing in melting point of F1, F2, F3 were due to the eutectic formation of paracetamol and other excipients Formula F3 (with 2% gelatin) showed the lowest melting point. DTA study showed that paracetamol enthalpy could not be determined because of the overlapping of endothermic peaks occured between paracetamol and other excipients.

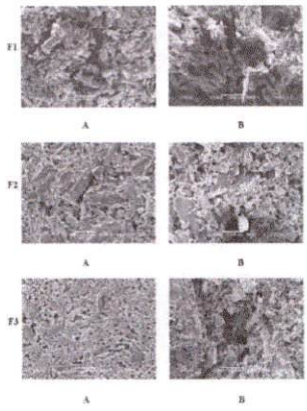

Figure 3. SEM photomicrograph of paracetamol ODT, tablet surface (A), tablet cross section (B)

Figure 3 showed the SEM photomicrograph of the paracetamol ODTs. F3 (gelatin 2%) showed the most subtle particles. This is due to the rigid nature of the gelatin. The characterization using SEM showed that paracetamol ODT prepared by freeze drying method was porous.

CONCLUSION

PXRD study demonstrated that there was significant decrease of paracetamol's intensity in the freeze dryed ODTs compared to the single compound of paracetamol, but there was no significant decrease between F2 (gelatin 1%) and F3 (gelatin 2%). DTA study showed that paracetamol enthalpy cannot be determined because of the overlapping of endothermic peaks occured between paracetamol and other excipients. The SEM photomicrograph showed that paracetamol ODTs prepared by freeze drying method were porous.

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