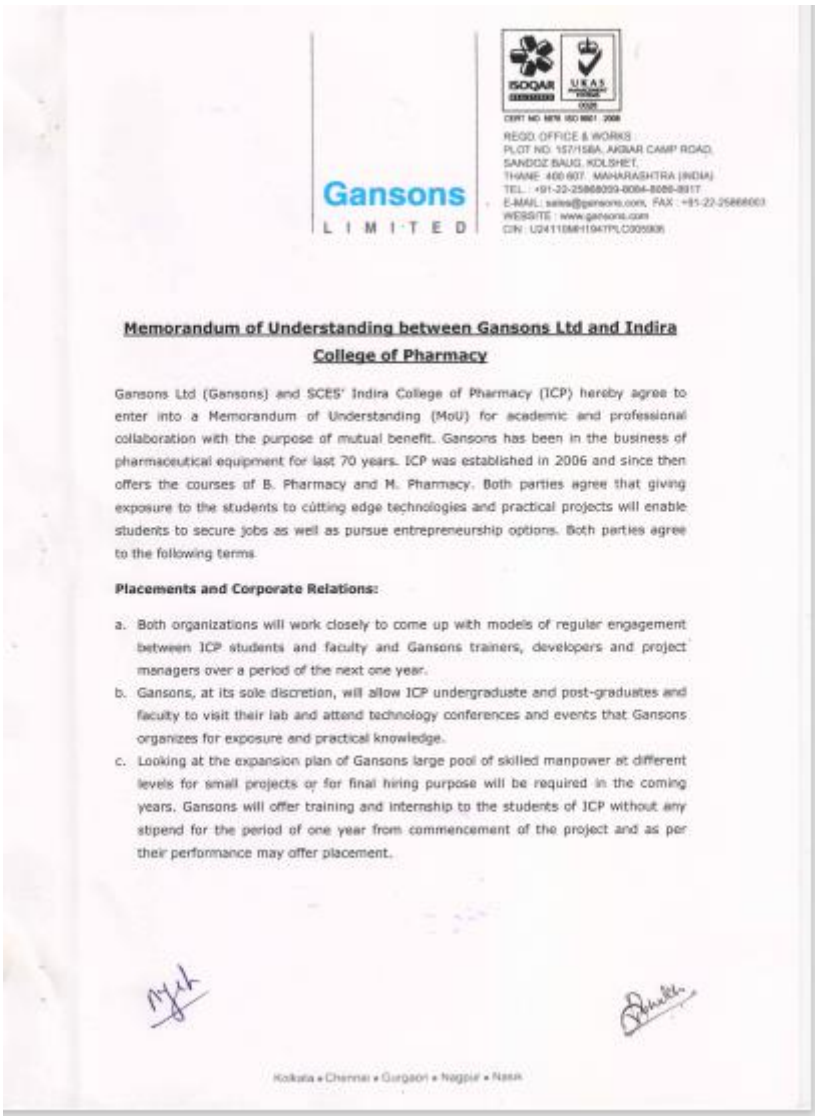
MOU

Gansons Limited

And

SCEs Indira College of Pharmacy

MOU



Gansons
LIMITED

REGD. OFFICE & WORKS :
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THANE 400 607. MAHARASHTRA (INDIA)
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WEBSITE : www.gansons.com
CIN: U24110MH1947PLC005808

Memorandum of Understanding between Gansons Ltd and Indira College of Pharmacy

Gansons Ltd (Gansons) and SCES' Indira College of Pharmacy (ICP) hereby agree to enter into a Memorandum of Understanding (MoU) for academic and professional collaboration with the purpose of mutual benefit. Gansons has been in the business of pharmaceutical equipment for last 70 years. ICP was established in 2006 and since then offers the courses of B. Pharmacy and M. Pharmacy. Both parties agree that giving exposure to the students to cutting edge technologies and practical projects will enable students to secure jobs as well as pursue entrepreneurship options. Both parties agree to the following terms

Placements and Corporate Relations:

a. Both organizations will work closely to come up with models of regular engagement between ICP students and faculty and Gansons trainers, developers and project managers over a period of the next one year.
b. Gansons, at its sole discretion, will allow ICP undergraduate and post-graduates and faculty to visit their lab and attend technology conferences and events that Gansons organizes for exposure and practical knowledge.
c. Looking at the expansion plan of Gansons large pool of skilled manpower at different levels for small projects or for final hiring purpose will be required in the coming years. Gansons will offer training and internship to the students of ICP without any stipend for the period of one year from commencement of the project and as per their performance may offer placement.

Kolkata • Chennai • Gurgaon • Nagpur • Nasik

Research:

a. Gansons and ICP will work together on joint research projects in areas of mutual interest. The objectives and scope of the projects would be as follows

Background:

Gansons Ltd. India and ICP intend to do collaborative projects using Gansons' machines. The main purpose will be to explore the innovations of these machines studying process parameters in product development.

Project Objectives:

ICP team will carry out a literature search for all the possible information that is relevant for formulation development using the machines. Based on the preliminary search, ICP team will work out the strategy for development and optimization of pharmaceutical formulations. Development of the formulation will start after approval and confirmation from Gansons that the proposed strategy is acceptable.

Project Scope:

Experimental work will be jointly undertaken at Gansons and ICP. The scope of activities involved is as follows:

- Formulation review and feasibility review/ proposal of strategy for formulation development.
- Literature summary along with formulation strategy will be submitted by ICP to Gansons who will approve of the strategy after considering status.
- Gansons will organise to procure required quantities of API, standards and impurities, etc. from the selected source (included in Project Cost).
- Formulation Development trials for selection of variant formulations.
- Development of analytical methods for assay of the dosage form.
- Development of dissolution method.
- Preparation of Product Development Reports, Master Manufacturing Formula, Optimization of trials, Analytical testing instructions, etc.

Terms & Conditions:

- Excipients will not be analysed by the students but the same will be used based on COA of the manufacturer.
- Cost of analysis at external laboratory (for XRD, Malvern, TGA, DSC, GC, etc), if required, will be charged to Gansons and the analysis will be co-ordinated and managed by ICP.
- The work carried out by ICP Research and Gansons will be for research purpose only.

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- The work carried out by ICP Research and Gansons will be for research purpose only.

- Notwithstanding anything contained anywhere in this agreement, including the clause hereinabove Gansons can make use of the case studies and project report for marketing and promotional purposes. Further, ICP cannot use the know-how obtained from this project for other use without the prior written permission of Gansons.

b. The research work undertaken jointly by ICP and Gansons will be published in reputed journals under the ownership of both the parties. In case of patentable research, both the parties would be the applicants of IPR and will share the benefits on equal basis.

c. Library and Lab facilities will be provided by ICP as and when required to Gansons employees on a prior notice for the research work. For the use of sophisticated instruments and equipment, no charges will be applicable.

d. Gansons will allow the students and faculty of ICP to use sophisticated instruments and equipment on a prior notice for the research work related to the projects being undertaken by the students for Gansons under this MoU. This kind help extended by Gansons will be duly acknowledged by the students and faculty in their research publications and dissertation.

e. Consultancy:

ICP believes in inviting and involving Corporate Professionals for Board of Advisors, Guest Lectures, Workshops, Seminars and similar events for which expert/s are required for enhancing knowledge, skills and attitude of faculty & students. To achieve this objective, whenever possible, Gansons will allow their professionals to visit ICP. ICP will also allow their faculty to visit Gansons for sharing their knowledge and expertise in the area of interest for Gansons.

f. Training:

Gansons and ICP will conduct Faculty Development Programmes (FDP), Refresher Courses for which Gansons will charge appropriately based on the number of participants in areas of mutual interest as mutually decided by the Gansons and ICP.

Gansons may conduct meetups / events / trainings at ICP. Gansons may charge external participants some participant fees. ICP students shall be having a right to preferred discounts, such as 20% or 30%, in such meetups/events/trainings and the revenue will be split 90:10 between Gansons:ICP. Further, the number of participants from ICP cannot be more than 5% of the total number of participants in that event.

All the promotional activities will be managed and marketing/faculty costs for meetups/ events/trainings shall be borne by Gansons whereas ICP shall bear the infrastructure

cost, admin costs and incidentals. Both parties will inform via email of the events and visits and seek prior permission from the other party.

g. Contact Persons

Dr. (Mrs.) Madhur Kulkarni will be the contact person for ICP to initiate, manage or execute any joint activities and Mr Samik Sen will be the contact person for Gansons.

For Gansons Ltd	For Indira College of Pharmacy
Mr Samik Sen AVP - Marketing Date:	Dr. (Mrs.) Anagha Joshi Principal Date:
Vishakha Rawal Executive - Marketing (On behalf of Samik Sen)	16/8/12

NON-DISCLOSURE AGREEMENT

THIS NON-DISCLOSURE AGREEMENT (this "Agreement") is made and entered into as of between Gansons Ltd., Mumbai and Indira College of Pharmacy(ICP), having its education setup at Niramay, S. No 89/2A, New Pune Mumbai Highway, Tathwade, Pune, Maharashtra – 411033.

Purpose: Gansons and ICP wish to explore opportunities in Training, Student Corporate Placement, Research, & consultancy of mutual interest and in connection with this opportunity wishes to execute this Non-Disclosure Agreement ("NDA").

1. **Confidential Information**: Confidential information means any information disclosed to by one party to the other, either directly or indirectly in writing, orally or by inspection of tangible or intangible objects, including without limitation documents, business plans, source code, software, hardware, application and uses of hardware and software, documentation, financial analysis, marketing plans, customer names, customer list, customer data. Confidential Information may also include information disclosed to a party by third parties at the direction of a Disclosing Party. Confidential Information shall not, however, include any information which the Receiving party can establish (i) was publicly known and made generally available in the public domain prior to the time of disclosure; (ii) becomes publicly known and made generally available after disclosure through no action or inaction of Receiving Party; or (iii) is in the possession of Receiving Party, without confidentiality restrictions, at the time of disclosure by the Disclosing Party as shown by Receiving Party's files and records immediately prior to the time of disclosure. The party disclosing the Confidential Information shall be referred to as "Disclosing Party" in the Agreement and the party receiving the Confidential Information shall be referred to as "Receiving Party" in the Agreement.

2. **Non-use and Non-disclosure**: The Receiving Party agrees not to use any Confidential Information for any purpose except to evaluate and engage in discussions concerning a potential business relationship between the parties hereto. Receiving Party agrees not to disclose any Confidential Information to third parties or to its employees, except to those employees who are required to have the information in order to evaluate or engage in discussions concerning the contemplated business relationship. The Receiving Party shall not reverse engineer, disassemble or decompile any prototypes, software or other tangible objects which embody the Disclosing Party's Confidential Information and which are provided to the Receiving Party hereunder.

3. **Maintenance of Confidentiality Information**: The Receiving Party agrees that it shall take all reasonable measures to protect the secrecy of and avoid disclosure and unauthorized use of the Confidential Information. Without limiting the foregoing, Receiving Party shall take at least those measures that Receiving Party takes to protect its own most highly confidential information and shall have its employees, if any, who have access to Confidential Information sign a non-use and non-disclosure agreement in content substantially similar to the provisions hereof, prior to any disclosure of Confidential Information to such employees. The Receiving Party shall not make any copies of Confidential Information unless the same are previously approved in writing by the Disclosing Party. The Receiving Party shall reproduce the Disclosing Party's proprietary rights notices on any such approved copies, in the same manner in which such notices were set forth in or on the original. The Receiving Party shall immediately notify the Disclosing Party in the event of any unauthorized use or disclosure of the Confidential Information.

4. **No Obligation**: Nothing herein shall obligate either party to precede with any transaction between them, and each party reserve the right, in its sole discretion, to

terminate the discussions contemplated by this Agreement concerning the business opportunity.

5. **No Warranty**: All confidential information is provided "as is". Neither party makes any warranties, express, implied or otherwise, regarding its accuracy, completeness or performance.

6. **Return of Materials**: All documents and other tangible objects containing or representing Confidential Information and all copies thereof which are in the possession of Receiving Party shall be and remain the property of the Disclosing Party and shall be promptly returned to the Disclosing Party upon the Disclosing Party's request.

7. **No License**: Nothing in this Agreement is intended to grant any rights to either party under any patent, mask work right or copyright of Company, nor shall this Agreement grant the receiving Party any rights in or to Confidential Information except as expressly set forth herein.

8. **Term**: This Agreement shall survive for a period of 2 years (renewable and extended up to 3 years) from the date of disclosure of the Confidential Information.

9. **Remedies**: The Receiving Party agrees that any violation or threatened violation of this Agreement will cause irreparable injury to the Disclosing Party, entitling the Disclosing Party to obtain injunctive relief in addition to all legal remedies.

10. **Miscellaneous**: This Agreement shall bind and inure to the benefit of the parties hereto and their successors and assigns. This document contains the entire agreement between the parties with respect to the subject matter hereof. Any failure to enforce any provision of this Agreement shall not constitute a waiver thereof or of any other provision hereof. This Agreement may not be amended, nor any obligation waived, except by a writing signed by both parties hereto. The parties have executed this Nondisclosure Agreement as of the date first above written.

For Gansons Ltd	For Indira College of Pharmacy
Mr Samik Sen AVP - Marketing Date:	Dr. (Mrs.) Anagha Joshi Principal Date:

On behalf of Samik Sen.

Vishakha Rawal.
Executive - Marketing.

SUMMARY

Shree Chanakya Education Society's

Indira College of Pharmacy, Pune

"Redefining Pharmacy Education"

NAAC : B++

Approved by PCI, AICTE, New Delhi, Affiliated to SPPU & MSBTE, Recognized by Govt. of Maharashtra

SUMMARY

Title: Activities carried out under MOU (Gansons)			
S.No.	Name of the Activity	Topic	Detail
1	Research Project	Formulation and evaluation of Ibuprofen granules in High shear Mixer granulator and supergran	Collaborative research project done by Dhanashree Bhondve, M. Pharm student
2	Poster Presentation	To compare quality of granules of ibuprofen obtained from super gran and rapid mixer granulator	19th International symposium on "Advances in Technology and Business Potential of Novel Drug Delivery System" organized by CRS IC
3	Research Paper	Development and evaluation of taste masked dry syrup formulation of potassium chloride	Kulkarni M et al, 5:1, AAPS Open, 2019
4	Poster Presentation	Development and evaluation of taste masked dry syrup formulation of potassium chloride	National seminar on "Excipients: The Key Drivers in Formulation Success"

Indira College of Pharmacy Pune

Dr. Anagha M Joshi
(Principal)

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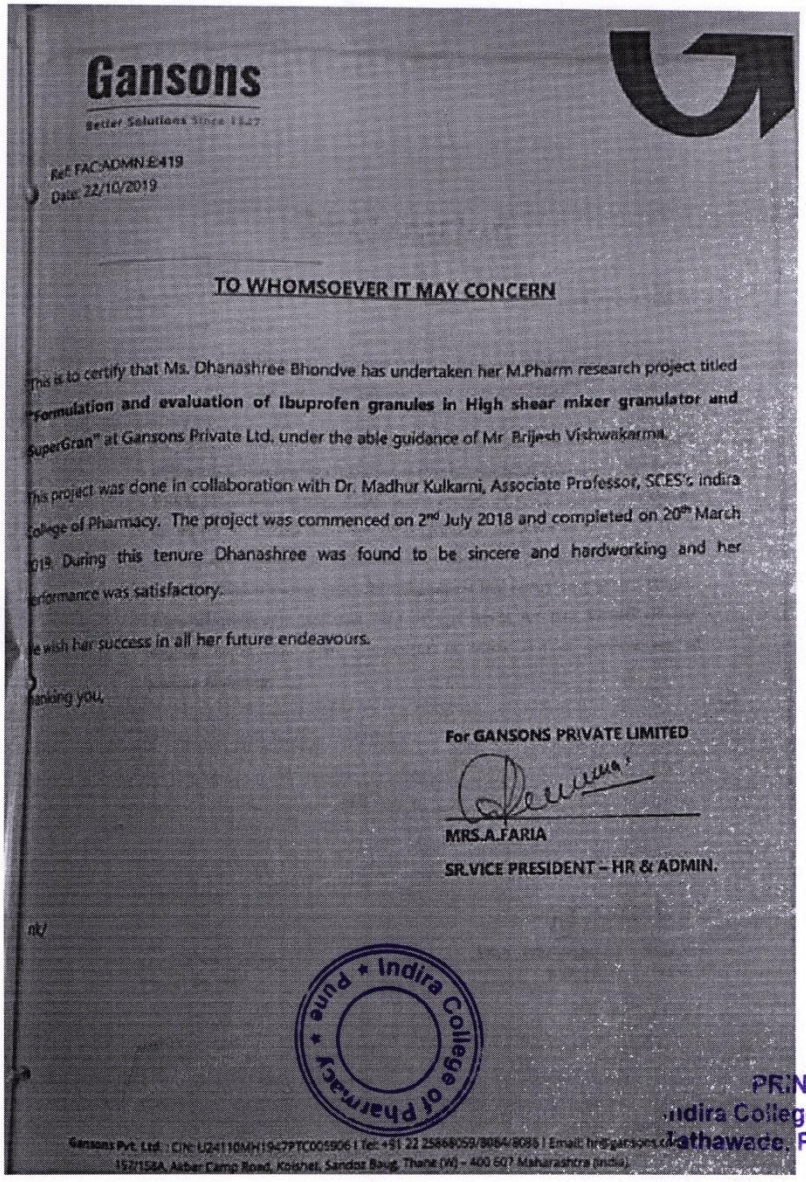
Tathawade, Pune - 411 033

Research Projects

Research Projects



Gansons

Better Solutions Since 1927

Ref: FAC:ADMN:E:419
Date: 22/10/2019

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms. Dhanashree Bhondve has undertaken her M.Pharm research project titled "**Formulation and evaluation of Ibuprofen granules in High shear mixer granulator and SuperGran**" at Gansons Private Ltd. under the able guidance of Mr. Brijesh Vishwakarma.

This project was done in collaboration with Dr. Madhur Kulkarni, Associate Professor, SCES's Indira College of Pharmacy. The project was commenced on 2nd July 2018 and completed on 20th March 2019. During this tenure Dhanashree was found to be sincere and hardworking and her performance was satisfactory.

We wish her success in all her future endeavours.

Thanking you,

For GANSONS PRIVATE LIMITED

MRS.A.FARIA
SR.VICE PRESIDENT – HR & ADMIN.

nk/

Indira College of Pharmacy * Pune *

Gansons Pvt. Ltd. : CIN: U24110MH1947PTC005906 | Tel: +91 22 25868059/8084/8085 | Email: hr@gansons.co.in
152/158A, Akber Camp Road, Kolshet, Sandoz Baug, Thane (W) – 400 607 Maharashtra (India).

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Poster Presentation

Poster Presentation

P-140

TO COMPARE QUALITY OF GRANULES OF IBUPROFEN OBTAINED FROM SUPER GRAN™ AND RAPID MIXER GRANULATOR

Bansude K., Kulkarni M., Bhondve D.
Niramay,S.No.89/2A, SCES Indira college of Pharmacy, New Pune Mumbai Highway,
Tathawade, Pune, Maharashtra-411033, India
Email: kiranbansude99@gmail.com

Keywords: Ibuprofen, Super Gran ™, Rapid Mixer Granulator

Introduction: Super Gran™ is a mixer cum granulator developed and patented by Gansons Ltd which is characterized by presence of multiple stacked impellor blades and two scrappers. The special design of the granulator is expected to enhance the speed of dry mixing, wet granulation and wet milling compared to rapid mixer granulator. This technology is expected to enhance the uniformity of granulation.
Aim: The aim of the present study was to compare quality of granules of ibuprofen (ibu) prepared in Super Gran™ and rapid mixer granulator (rmg).
Objectives: 1.To prepare ibu granules using various diluents and granulating agents in Super Gran ™ and rmg 2. To compare the granules obtained from both the granulators 3. To compare tableting characteristics of both the granules **Methodology:** Ibu granules were prepared by wet granulation technique using various trial compositions.(Table 1)For each composition, dry mixing and wet granulation were carried out in rmg (Bectochem)and Super Gran™. The resulting granules were compared for flow properties, proportion of fines and morphology. The granules were compressed into tablets using 12mm s/c circular plain punches (Rimek, Karnavati). The tablets were evaluated for appearance, weight variation, hardness, friability, disintegration time. *In vitro* release profiles (conducted as per USP monograph) were compared using Student's t test. 2^2 Full Factorial design was used for optimization trials of ibu tablets in both SuperGran™ and rmg. Independent variables chosen were concentration of binders (maize starch and PVP K-30). The response variables were disintegration time (<3 mins) and *in vitro* release (not less than 80% within 60 mins). Total 7 trial runs (A1-A7 and S1-S7) suggested by Design Expert Software® (Version 11) were processed in both the granulators, granules were compressed and the tablets were evaluated for all the earlier mentioned parameters.

Ingredients	Quantity in mg/tab					Binder Proportions	B1/B1	B2/B2	B3/B3	B4/B4	B5/B5
	B1/B1	B2/B2	B3/B3	B4/B4	B5/B5						
						Povidone K-30	27.27	-	-	-	-
						Starch maize	-	33	-	43.7	43.70
Dry Mixing						Purified water	q.s	q.s	q.s	q.s	q.s
Ibuprofen	400	400	400	400	400	Starch dried	-	40	-	40	40
Lactose	26	-	115	-	-	Aerosil 200	2.5	7.45	-	7.45	7.45
Microcrystalline Cellulose	88	-	-	-	-	Extragranular	B1/B1	B2/B2	B3/B3	B4/B4	B5/B5
						Stearic acid	-	1.50	-	1.50	1.50

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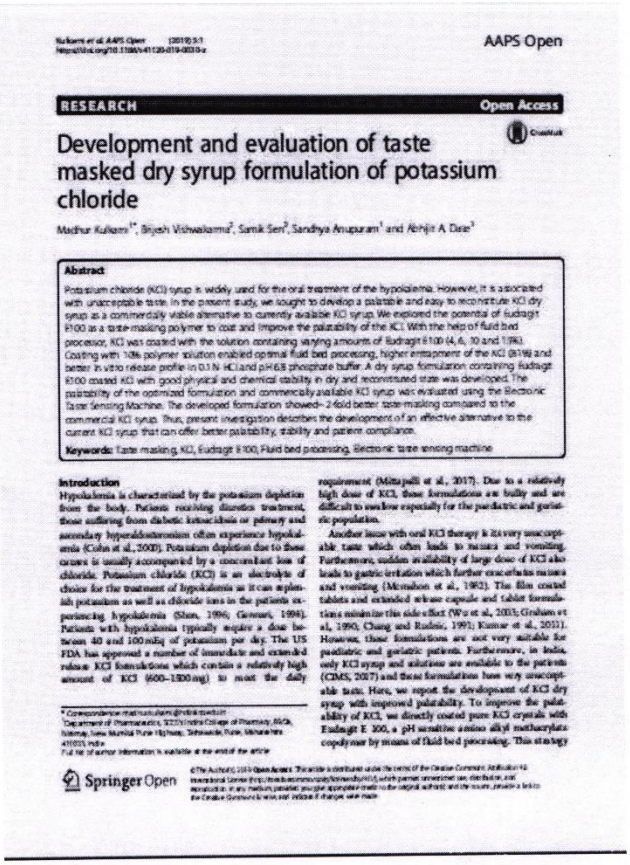
Research Paper

Research Paper



Kulkarni et al. AAPS Open (2019) 5:1
https://doi.org/10.1186/s41120-019-0033-z

AAPS Open

RESEARCH Open Access

Development and evaluation of taste masked dry syrup formulation of potassium chloride

Madhur Kulkarni[1*], Brijesh Vishwakarma[2], Samik Sen[2], Sandhya Anupuram[1] and Abhijit A Date[3]

Abstract

Potassium chloride (KCl) syrup is widely used for the oral treatment of the hypokalemia. However, it is associated with unacceptable taste. In the present study, we sought to develop a palatable and easy to reconstitute KCl dry syrup as a commercially viable alternative to currently available KCl syrup. We explored the potential of Eudragit E100 as a taste-masking polymer to coat and improve the palatability of the KCl. With the help of fluid bed processor, KCl was coated with the solution containing varying amounts of Eudragit E100 (4, 6, 10 and 12%). Coating with 10% polymer solution enabled optimal fluid bed processing, higher entrapment of the KCl (81%) and better in vitro release profile in 0.1 N HCl and pH 6.8 phosphate buffer. A dry syrup formulation containing Eudragit E100 coated KCl with good physical and chemical stability in dry and reconstituted state was developed. The palatability of the optimized formulation and commercially available KCl syrup was evaluated using the Electronic Taste Sensing Machine. The developed formulation showed~ 2-fold better taste-masking compared to the commercial KCl syrup. Thus, present investigation describes the development of an effective alternative to the current KCl syrup that can offer better palatability, stability and patient compliance.

Keywords: Taste masking, KCl, Eudragit E100, Fluid bed processing, Electronic taste sensing machine

Introduction

Hypokalemia is characterized by the potassium depletion from the body. Patients receiving diuretic treatment, those suffering from diabetic ketoacidosis or primary and secondary hyperaldosteronism often experience hypokalemia (Cohn et al., 2000). Potassium depletion due to these causes is usually accompanied by a concomitant loss of chloride. Potassium chloride (KCl) is an electrolyte of choice for the treatment of hypokalemia as it can replenish potassium as well as chloride ions in the patients experiencing hypokalemia (Shen, 1996; Gennari, 1998). Patients with hypokalemia typically require a dose between 40 and 100 mEq of potassium per day. The US FDA has approved a number of immediate and extended release KCl formulations which contain a relatively high amount of KCl (600–1200 mg) to meet the daily requirement (Mittapelli et al., 2017). Due to a relatively high dose of KCl, these formulations are bulky and are difficult to swallow especially for the paediatric and geriatric population.

Another issue with oral KCl therapy is its very unacceptable taste which often leads to nausea and vomiting. Furthermore, sudden availability of large dose of KCl also leads to gastric irritation which further exacerbates nausea and vomiting (Memahon et al., 1982). The film coated tablets and extended release capsule and tablet formulations minimize this side effect (Wu et al., 2003; Graham et al., 1990; Chang and Rudnic, 1991; Kumar et al., 2011). However, these formulations are not very suitable for paediatric and geriatric patients. Furthermore, in India, only KCl syrup and solutions are available to the patients (CIMS, 2017) and these formulations have very unacceptable taste. Here, we report the development of KCl dry syrup with improved palatability. To improve the palatability of KCl, we directly coated pure KCl crystals with Eudragit E 100, a pH sensitive amino alkyl methacrylate copolymer by means of fluid bed processing. This strategy

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Full list of author information is available at the end of the article

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Poster Presentation 2

Poster Presentation

DEVELOPMENT AND EVALUATION OF TASTE MASKED DRY SYRUP FORMULATION OF POTASSIUM CHLORIDE (KCL)

Gadre T.,Tandale K., Kulkarni M, Anupuram S., Vishwakarma B.
Niramay, S.No. 89/2 A, SCES Indira college of Pharmacy, New Pune Mumbai Highway, Tathawade, Pune, Maharashtra-411033, India
Email : tjtejashri2522@gmail.com

Aim: The aim of the present study was to develop and evaluate taste masked dry syrup formulation of KCl.

Objectives –

1. Coating of KCl with Eudragit E 100, a pH sensitive amino alkyl methacrylate copolymer by means of fluid bed process
2. Development of dry syrup formulation of coated KCl
3. Comparison of developed formulation with marketed syrup for *in vitro* dissolution parameters and taste masking aspect.

Methodology: Fluid bed coating of KCl was performed using 4, 6, 10 and 15% coating solutions of Eudragit E100. Process parameters like spray rate, inlet air temperature, bed temperature and atomizing air pressure were optimized The 4 lots of drug coated using solutions containing 4%, 6%, 10% and15% of Eudragit E 100 were termed as C1, C2, C3 and C4 respectively. They were subjected to evaluation of microscopy, particle size analysis, flow properties, SEM, assay, entrapment efficiency and *in vitro* dissolution studies in 0.1 N HCl and pH

Reconstituted formulation was subjected to organoleptic evaluation, redispersibility, sedimentation volume, assay and *in vitro* dissolution in both 0.1N HCl and 6.8 phosphate buffer on day 1, 2,3 and 7 of reconstitution. The developed formulation and the marketed syrup formulation were compared for their dissolution behavior and the palatability aspect using electronic taste sensing machine. Optimized formulation was filled in clear glass bottles, capped and subjected to accelerated conditions of 40±2 °C and 75% ±5% RH.

Results: Coating with 10% polymer solution (composition C3) enabled optimal fluid bed processing, higher entrapment of the KCl (81%) and better *in vitro* release profiles in 0.1N HCl and pH 6.8 phosphate buffer. Whereas, coating with higher concentration of polymer resulted in sticking and agglomeration of particles. *In vitro* release in 0.1N HCl was more than 95% within 30 minutes throughout the 7 days. Marketed syrup formulation upon subjecting to dissolution studies in 0.1 N HCl showed complete dissolution of drug within 5 minutes unlike the

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