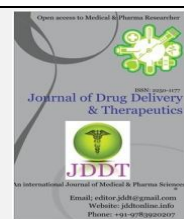




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Review Article

A brief review on Kollidon

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ABSTRACT

Polyvinylpyrrolidone includes soluble and insoluble grades; soluble grades are synthesised by the mechanism of polymerization, the free radical polymerization into the water by using hydrogen peroxide as an initiator, the mechanism which terminates the polymerisation reaction makes it probable to produce soluble polyvinylpyrrolidone of about any molecular weight. Cross-linked polymer shows yield through popcorn polymerisation of an N-vinylpyrrolidone which gets insoluble polyvinylpyrrolidone. Kollidon is in the market as a brand name for polyvinylpyrrolidone, a kollidon family now is a set of common excipients based on polyvinylpyrrolidone for use in the pharmaceutical industry. They have a great variety of applications in an oral formulation; the functions of oral formulation encompass fast disintegration, sustain drug release, solubility, bioavailability enhancement, and stabilize the active ingredient. Kollidon containing a mixture of polyvinyl acetate plus povidone are generally used in the formation of sustained release formulation. Owing to their high molecular weight, are recognized as a suitable vehicle for producing sustained release drug delivery system. In this review paper, applications of different grades of kollidon are organized in the form of tables and reviewed critically. Current literature of patents on kollidon based formulations is also presented.

Keywords: Polyvinylpyrrolidone, polymerization, sustained release drug delivery

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1. INTRODUCTION

Kollidon grades among the synthetic excipient it is said to be one of the essential substances in the pharmaceuticals and cosmetic industries. The soluble kollidon grades were synthesized by w. reppe in 1939; a number of the product followed by including insoluble grades, copolymeristates and sustain release preparation for numerous applications. The insoluble grades (crospovidone) are prepared using a physical cross-linking process as popcorn polymers of vinyl pyrrolidone. kollidon VA 64 (Copovidone) is a water-soluble copolymeristate of vinylpyrrolidone, and vinyl acetate is mainly used as a binder in tablet, granules, capsules, and coating process. For sustained release purpose, a mixture of polyvinyl acetate and povidone in a ratio of 8:2 is available under the name of kollidon SR which mainly used as controlled release system. Kollidon soluble grade has a wide range of applications in the oral formulation include enhancement in solubility and bioavailability of the drug, immediate release, taste masking, increase binding capacity, stability, improve the activity of pore formation. The examples of soluble grade of kollidon (Povidone) are kollidon 12 PF, 17 PF, 25, 30, 90F, kollidon VA64 (Copovidone), insoluble grade (Crospovidone) are kollidon CL, CL-F, CL-SF, CL-M and kollidon SR grade which is mixture of polyvinyl acetate and povidone in ratio of 8:2 for sustain

release purpose. All the above grade of kollidon has broad application in formulation and development. However, in the current review, we have focused critically on applications of following grades of kollidon vis kollidon soluble (12PF, 17PF, 30, 90, VA64), kollidon insoluble (CL-M, CL-F, CL-SF), and kollidon SR. The grades on which spacious research has been published were selected for review. Hence the objective of the present manuscript is to make a compilation review of research publications and patents on various applications of some chosen grades of kollidon.[1]

1.1. Soluble kollidon grades (Povidone)

The following are the examples of soluble kollidon categories such as kollidon 12, 12PF, 17PF, 25, 30, 30LP, 90F. Amongst the above categories, Kollidon 12PF, 17PF, 30, 90 were selected for review as these having research literature published on it.

1.2. kollidon® 12PF, 17PF

The low molecular grades, kollidon 12PF, 17PF are intended for solubilising agents, dispersants and crystallisation inhibitors particularly for injectable

A current literature review on kollidon 12PF **Gayathri K et al.** [2] shows that Kollidon 12PF which is having low molecular weight polyvinylpyrrolidone generally used as a

solubilizing agent and also inhibits crystallization used in the preparation of immediate release formulations and also reducing printing temperature in 3D printing method in order to hold thermolabile and less melting temperature drugs. **L. S. May et al.** [3] prepared a solid dispersion of docetaxel utilising binary and ternary method using Kollidon 12PF, Soluplus, Lutrol F68 and hydroxyl propyl beta-

cyclodextrin in various weight proportions. **Piero Piccioni et al.** [4] He studied screening systems for initial stage formulation development by solubility parameter using the solid dispersion of itraconazole with hot melt extrusion and quench cooling technique by using kollidon 17PF, Eudragit E (EPO) and Soluplus.

Table 1: The reported literature on Kollidon 12PF, 17PF.

Name of the drug	Method	Dosage form	Result	Ref
Ramipril	Low temperature fused deposition modelling (FDM) 3D printing of thermolabile drugs	Drug-loaded filament	Enhance solubility of the drug	[5]
Docetaxel	Binary and ternary solid dispersion	Solid dispersion	Enhanced solubility of the drug	[3]

1.3 Kollidon® 30

W. Linka. [6] studied the three formulations of matrices show the usefulness of Kollidon K30 and HPMC in the technology of hydrophilic matrices with ketoprofen, Kollidon K30 accelerated the release of ketoprofen from tablets of formulation

1.4 Kollidon® 90F

Kollidon 90F having various properties like high binding capacity the required quantity is 2% or even less, stabilisation of oral dosage form, film-forming agent, kollidon 90F having good solubility in water and alcohol it can be used as a thickener for an aqueous-alcoholic solution for oral application

A current literature review on kollidon 90F **A. Fini et al.** [7]used kollidon90Fwith combination of appropriate excipient for obtaining taste masking, orally disintegrating tablets and delay the release of ibuprofen using conventional and straightforward techniques. **Dashevsky et al.** [8]he used Polyvinylpyrrolidone (Kollidon90F) superior to HPMC and HPC as a binder for the swelling layer about binding (adherence to capsule) and increase disintegration properties of the dosage form. **B.B. Alsulays et al.** [9]studied the influence of the molecular weight of carriers and processing parameters on the extrudability, drug release, and stability of fenofibrate formulations processed by hot-melt extrusion.

Table 2: The reported literature on kollidon30, 90F.

Name of the drug	Method	Dosage form	Result	Ref
ketoprofen	Direct compression	Tablet	Enhanced the release of drug from tablet	[10]
ibuprofen	Orally disintegrating and delayed release Capsule-Based Drug Delivery System with Pulsatile Drug Release	Tablet Capsule	Delayed the release and masked taste of the bitter drug Increased binding capacity to adhere capsule	[7]

1.5 Insoluble kollidon grades(Crospovidone)

Crospovidone, a hydrophilic crosslinked homopolymer of N-vinyl pyrrolidone, has been reported as one such alternative. Based on its porosity as well as its ability to rapidly absorb water, swell, and yet remain insoluble, it is a biologically inert, synthetic polymer whose synthesis does not involve any organic solvents a polymerisation process in water manufactures the Kollidon CL grades without any organic solvents. This polymerisation produces a mainly physically cross-linked insoluble polyvinylpyrrolidone in the form of a popcorn polymer. There are various grades of Kollidon CL, CL-F, CL-SF, and CL-M. Among this grade CL-M, CL-F, CL-SF was selected because most of the literature are published on these grade showing increase in solubility, bioavailability, immediate release of drug from dosage, increase sphericity of pellets, etc.

1.6 Kollidon® CL-M

KollidonCL-Misused as the standard disintegrant for all kind of different tablet formulations Main reasons for selection of

kollidon CL-M is the strongest disintegration power with benefits, especially in large tablets. It has advantages compared to other disintegrants which are dependent on different chemistry due to disintegration and dissolution speed.

A literature review on kollidon CL-M shows that it has been used extensively in the formulation of **A. Maroni et al.** [11]studied Preliminary study on free and applied films in which Kollidon CL-M was used as superdisintegrant and shows the activity of pore-formation in multi-unit pulsatile drug delivery system. **Y. Gonnissen et al.** [12]studied the effect of maltodextrins and superdisintegrants on the tablet properties and evaluated directly compressible powders co-processed via spray drying. The disintegration time of tablets containing a coprocessed superdisintegrant (kollidon CL-M) was longer than other excipients.**H. Friedrich et al.** [13]improved the dissolution rate of carbamazepine and nifedipine by adsorbing solutions of the drugs in hydrophilic nonvolatile or volatile solvents onto carriers (Aerosil, Kollidon CL-M) with a large surface area.

Table 3: The reported literature on kollidon CL-M.

Name of the drug	Method	Dosage form	Result	Ref
Acetaminophen	Pulsatile drug delivery	Capsule	Increase the activity of pore-formation	[14]
Acetaminophen	Direct compression co-processed via spray drying	Tablet	Increase in disintegration time of formulation	[12]
Carbamazepine and nifedipine	Absorbent system	Tablet	Increase the dissolution rate and drug release from the formulation	[13]

1.7 Kollidon® CL-F, CL-SF

Kollidon CL-SF is the most excellent croscopovidone grade for disintegration purposes, and it has a good disintegration power and fewer surface defects of the tablets after humid storage. This grade is perfect for fast disintegrating buccal tablets

A current literature review on kollidon CL-SF based research publication *N. C. Loka et al.* [15] shows that immediate release pellets were prepared by wetted mass extrusion method, and markedly improved the sphericity of the pellets produced by marumerization. *A. Amelian et al.* [16] formulated orally disintegrating loratadine tablet manufactured with co-processed mixture (Kollidon CL-F, CL-SF) by direct compression method, prepared tablets was of

appropriate mechanical properties, disintegration time below 30 seconds was observed in formulation with croscopovidone as disintegrant. *M. Saurabh et al.* [17] studied an integrated, quality by design (QbD) approach for design, development, and optimization of an orally disintegrating tablet formulation of carbamazepine; he found that kollidon CL-SF concentration was optimum to prepare orally disintegrating tablet formulation of carbamazepine of desired attributes; thus it was found to be best sublimating agent and disintegrant, respectively. *R. Sheshala et al.* [18] formulated orally disintegrating tablets of sumatriptan succinate, the formulation containing kollidon CL-SF disintegrated in the oral cavity within 41 s and released more than 90% of the drug within 15 minute.

Table 4: The reported literature on kollidon CL-F, CL-SF.

Name of the drug	Method	Dosage form	Result	Ref
Caffeine	Extrusion spherization	Pellets	Improve in sphericity of pellets	[19]
Loratadine	Direct compression	Orally disintegrating tablet	Improved mechanical properties of tablet and disintegration time	[16]
Carbamazepine	Direct compression	Orally disintegrating tablet	Improved in disintegration time of formulation	[17]
Sumatriptane succinate	Direct compression	Orally disintegrating tablet	Improved in disintegration time of formulation	[20]

1.8 Kollidon® SR

Kollidon SR is spray dried polyvinyl acetate containing also soluble poly-vinylpyrrolidone (povidone) in the ratio 8:2, kollidon SR is nominally an 80/19 (w/w) mixture of polyvinyl acetate and polyvinylpyrrolidone, respectively. Kollidon SR can be used for the production of the sustained release matrix preparations of tablets, pellets, and granules. The recommended technology for the production of sustained release matrix tablets based on Kollidon SR is the direct compression. The excellent flowability and compressibility of Kollidon SR are the main factors which make this excipient particularly suitable for the manufacture of sustained release matrix tablets obtained by direct compression

An updated literature review on Kollidon SR based formulations revealed that it could be used in sustaining the release, bioavailability enhancement of drugs. *M. Shergill et al.* [21] formulated sustained release solid dispersion oral tablet containing water-insoluble drug by using kollidon SR, and another excipient, shows enhanced solubility of drug while also sustaining its release. *Özgüney et al.* [22] prepared extended release kollidon SR mini-matrices by hot-melt extrusion, kollidon SR were used as the carrier for drug which shows plasticizing effect, and hot-melt extruded

successfully prepared using kollidon SR. *Meulenaar et al.* [23] kollidon SR used for preparation of an extended-release formulation of capecitabine by using In Vitro-In Vivo correlating modelling, kollidon SR in this formulation used as carrier for spray drying. *W. Sakr et al.* [24] studied effect of Kollidon SR comparison with other polymers on the release of Albuterol Sulphate from matrix tablets, he studied kollidon SR with combination of (HPMC and Carboxypol) were found to be potential candidates for the development of extended release of Albuterol Sulphate matrix tablets, also found that kollidon SR to be a useful release rate modifier for highly water-soluble low dose drug. *S.H. Song et al.* [25] formulated controlled-release pelubiprofen tablet using kollidon SR, kollidon SR containing formulation was found to be the most promising and stable for 6 months in an accelerated stability test and 24 months in a long-term storage test. Control release achieved from the tablet was limited at pH 1.2, but gradually increased at pH 6.8 with a surface-erosion was studied. *Sahoo et al.* [26] formulated sustained-release dosage form of verapamil hydrochloride by solid dispersion technique using eudragit RLPO and kollidon SR, drug release study from dosage form was studied, kollidon containing dosage form was extended till 8 hr. *J.L. Arias et al.* [27] studied the dosage form containing kollidon SR colloidal particles which were used as vehicles

for oral morphine delivery in pain treatment, also analysed that the release studies showed a biphasic profile very suitable to achieve a sustained release of morphine during 24 h. Therefore, they have concluded that kollidon SR suspensions are very promising candidates for the formulation of oral morphine systems with a sustained release. **E. Palazi et al.** [28] enhanced solubility of water-insoluble drug felodipine by melt-extrusion process and sustained release action of drug was achieved using kollidon SR. **C. Wiranidchapon et al.** [29] investigated the effect of storage temperature on drug release from matrices containing ibuprofen in Kollidon SR, the matrix tablets were produced by direct compression and then kept at 30 and 45°C for 3 months. **Magdalena Czajkowska et al.** [30]

formulated Prolonged-release mini tablets with carbamazepine Prolonged release of carbamazepine was obtained from both matrix-type by using kollidon SR. **S. Engineer et al.** [31] studied the effects of temperature and humidity on tablets containing diphenhydramine hydrochloride which was prepared using direct compression technique with Kollidon SR; sustained-release tablets composed of Kollidon SR have been shown to be heat and moisture sensitive. **J. Grund et al.** [32] studied the kollidon SR and other polymer properties on direct compression and drug release from water-insoluble controlled release matrix tablets and compared with regard to their properties in dry and wet state.

Table 5: Reported literature on kollidon SR.

Name of the drug	Method	Dosage form	Result	Ref
Disulfiram	Hot-melt extrusion	Solid dispersion tablets	Enhanced solubility of drug while also sustaining its release	[33]
Ibuprofen, theophylline	Hot-melt extrusion	Tablet	Shows plasticising effect and extended the drug release	[22]
Capecitabine	Spray drying, co-spray drying	Tablet	Co-spray drying was successfully achieved	[23]
Albuterol Sulphate	Direct compression	Tablet	Kollidon SR was found to enhance the mechanical properties of tablets increasing hardness and decreasing friability.	[34]
Pelubiprofen	Wet granulation	Tablet	Stability was achieved and controlled the release of the tablet at 1.2 pH.	[35]
Verapamil hydrochloride	Solid dispersion, tablets were compressed with hydraulic pellet press.	Tablet	Tablet extends the release of drug till 8hr by using kollidon SR.	[36]
Morphin hydrochloride	Incorporation	Oral Suspension	Sustained the release of drug	[27]
Felodipine	Hot-melt extrusion	Amorphous solid dispersion	Solubility was enhanced as well as sustained the release of drug by using kollidon SR.	[37]
Ibuprofen	Matrix tablet prepared by direct compression	Matrix tablet	Stability of ibuprofen seems to be increased under various conditions.	[29]
Carbamazepine	Direct compression	Matrix mini tablet	Prolonged the release of drug by matrix tablet prepared using kollidon SR	[30]
Diphenhydramine HCL	Direct compression	Tablet	shows heat and moisture sensitivity	[31]

1.9 Kollidon®VA64 (Copovidone)

The Kollidon VA 64 is manufactured by free-radical polymerisation of 6 parts of N-vinylpyrrolidone and 4 parts of vinyl acetate in 2-propanol, it has pH 3 – 7 (10 % in water), Kollidon VA 64 in formulations for solid dosage forms, the particle size distribution can be of considerable importance. This particularly applies to the manufacture of tablets. However, it also has important in solutions, e. g. film-coating solutions for tablets, as the dissolution rate and the dusting properties depend on the proportions of coarse and fine particles respectively, it has good binding and film-forming properties, their affinity to hydrophilic and hydrophobic surfaces and the relatively low hygroscopicity. Because of these properties, copovidone is used as a binder in the production of granules and tablets by wet granulation, as a dry binder in direct compression, as film former in coatings on tablets, as a protective layer and sub coat for

tablet cores, as a film-forming agent in sprays and as a matrix.

Current literature review on kollidon VA64 revealed that mostly solid dispersions were prepared to increase solubility and bioavailability of water-insoluble drugs. **K. Chmiel et al.** [38] identified physically stable concentration of amorphous solid dispersion in case of Flutamide with Kollidon VA64. **R. Dreu et al.** [39] formulated multiple-unit tablet containing enteric coated pellets by using kollidon VA64 as binder, kollidonVA64 was found to be optimal as a cushioning excipient. **T. Vojinovic et al.** [40] prepared ternary solid dispersions with hydrophilic polymer kollidon VA64 and surface adsorbent for improving dissolution rate of carbamazepine, he analyzed that ternary solid dispersion prepared with kollidonVA64 hydrophilic polymer and adsorption carrier resulted in significant improvement of carbamazepine dissolution rate. **F. Tres et al.** [41] studied the pH-dependent controlled release of indomethacin by using

kollidonVA64; the experiments were performed at pH 2 to mimic the stomach conditions and pH 6.8 to simulate the post-stomach conditions. He found that only indomethacin present in the 5% extrudate exhibits a detectable dissolution rate at pH 2, pointing to a drug release mechanism dependent on the highly water-soluble copovidone. He also analysed that the proposed pH-dependent dissolution model can be applied to a wide range of poorly soluble ionizable drugs and may be employed in the future to control and modulate the drug release in the stomach and small intestine. **Maddineni et al.** [42] studied, melt extrusion technology in combination with Kollidon VA 64 produced chemically and physically stable extrudates with higher drug loading and enhanced drug release. Nifedipine was found to be miscible in Kollidon VA 64 up to 40% w/w drug loading without demonstrating the need for any processing aids. **R. S. Chaudhary et al.** [43] kollidon VA 64 and a combination of Kollidon VA 64 with Kollidon VA 64 fine as an excipient in direct compression process of tablets, the combination of the two grades of material was evaluated for capping, lamination, and excessive friability. He found that tablets with hardness ranging between 19 and 21 kp, with no friability, capping, or lamination issue. **D. Patel et al.** [44]

formulated user-friendly metered-dose transdermal spray (MDTS) of lopinavir; he found that formulation containing 5 %w/v of Kollidon VA 64 had best sprayability and volatilisation property. Significantly increase in permeation enhancement and steady-state transdermal flux. **K. Kolter et al.** [45] studied structure and dry binding activity of different polymers, including kollidon VA 64, the tablets prepared using kollidon VA 64 showed an improvement in mechanical properties (hardness, friability) with increasing dry binder concentration and greatest binding efficacy. **E. Castellanos Gil et al.** [46] formulated oral controlled delivery system for propranolol hydrochloride by using wet granulation process. He studied the ability of subcoating with Kollidon VA 64 as a barrier to water penetration in matrix cores; he observed that kollidon VA 64 not only increases the mechanical properties of tablets (less friability) but also reduces the amount of absorbed water from the air in tropical stability condition. **N. Solanki et al.** [47] formulated 3D printed tablet for rapid drug release by fused deposition modelling (FDM): screening polymers for drug release, drug-polymer miscibility, and printability, he found that mixture of Kollidon VA64 and Affinisol 15 cP is suitable polymer system for 3D printing and rapid drug release.

Table 6: The reported literature on kollidon VA 64

Name of the drug	Method	Dosage form	Result	Ref
Flutamide	Solid dispersion	Amorphous solid dispersion	The amorphous solid dispersion was identified as physically stable	[38]
Carbamazepine	Ternary solid dispersion	Amorphous solid dispersion	The result showed improvement of carbamazepine dissolution rate	[40]
Indomethacin	Extrusion spheronization	Extrudes	the pH-dependent controlled release of indomethacin was carried out successfully	[41]
Celecoxib	melt-quenching	Amorphous solid dispersion	Increase in bioavailability was determined.	[48]
Nifedipine	Hot-Melt Extrusion	Extrudes	Produced physically and chemically stable extrudes with enhanced flow characteristics and excellent stability.	[49]
Esomeprazole Magnesium	Direct compression	Tablet	By using kollidon VA 64 friability, capping, or lamination issue were minimised.	[50]
Lopinavir		Metered-dose transdermal spray	Good sprayability, the formulation was stable, and the permeation rate was enhanced by using kollidon VA 64	[51]
Dicalcium phosphate formulation (water-insoluble) and vitamin C (Water soluble) was used for the study.	Direct compression	Tablet	Shows increase in dry binder concentration and greatest binding efficacy.	[45]
Propranolol hydrochloride	Wet granulation	Tablet	Kollidon VA 64 increase mechanical properties of tablet and also stability	[46]
Nimodipine	Hot-Melt Extrusion	Solid dispersion	Effect of high storage temperature on the recrystallisation rate during the dissolution of Nimodipine-Kollidon VA64 solid dispersions	[52]
Haloperidol	Hot-Melt Extrusion	3D printed tablet	Enhanced drug release	[53]

1.10 Patents on kollidon based formulations

Patents on kollidon based formulations are presented in Table. Patents were filed on the applications of various grades of kollidon-vis. These grades were used in the formulation of drugs with diverse applications such as improvement in solubility, bioavailability, enhanced absorption, etc. **P. Pilgaonkar et al.** [54] patented the novel sustained release dosage form comprising an active agent and a combination of a non-swelling pH-dependent release retardant and a non-swelling pH-independent release retardant polymer which provides pH-independent drug release for a considerable period of time after administration, kollidon SR used as sustained release polymer and also other kollidon grades were used in the preparation of formulation. **V. Kanikanti et al.** [55] patented solid pharmaceutical formulation with delayed release, the invention relates to a solid pharmaceutical preparation with delayed release of the active ingredients which is suitable in particular for use in animals. Kollidon SR used as delayed release polymer in combination with other excipients. **K. Kolter et al.** [56] patented active ingredient-containing floating forms comprising polyvinyl acetate and

polyvinylpyrrolidone, their use, and production, invention relates to oral dosage forms comprising one or more active ingredients, a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone, where appropriate other excipients for producing the dosage form, wherein they float on gastric fluid and display delayed release of active ingredient. **Talwar et al.** [57] patented an orally administered controlled drug delivery system providing temporal and spatial control; the Swelling agent belongs to a class of compounds known as superdisintegrants (e.g., cross-linked polyvinylpyrrolidone) used as an immediate release component in the present invention. **Roser et al.** [58] patented rapidly soluble oral solid dosage forms, methods of making same, and compositions thereof; in this invention kollidon and its grades were used as a binder in the formulation. **Bockbrader et al.** [59] patented solid pharmaceutical compositions containing pregabalin; the composition includes a matrix forming agent and a swelling agent and is suitable for once-daily oral administration. The exemplary matrix forming agents include mixtures of polyvinyl acetate and polyvinylpyrrolidone, and exemplary swelling agents include cross-linked polymers of polyvinylpyrrolidone.

Table 7: Patents on kollidon based formulations.

Title	Patent no	Date	Kollidon grade	Inventors
Novel sustained release dosage form	United states patent US 2009/0053310 A1	26/02/2009	Kollidon SR, VA 64, K30	[54]
Solid pharmaceutical formulation with delayed release	United States patent US 2011/0046072 A1.	24/02/2011	Kollidon SR	[55]
Active ingredient-containing floating forms comprising Polyvinylacetate and Polyvinylpyrrolidone, their use and production	United states patent US 6,635,279 B2	21/10/2003	Kollidon SR	[56]
an orally administered controlled drug delivery system providing temporal and spatial control	United States patent US 6,261,601 B1	17/07/2001	Kollidon CL-M	[57]
patented rapidly soluble oral solid dosage forms, methods of making same, and compositions thereof	United States patent US 5,762,961	09/06/1998	Kollidon VA 64	[58]
solid pharmaceutical compositions containing pregabalin	United states patent US 8,945,620 B2	03/02/2015	Kollidon SR	[59]

CONCLUSION

Kollidon is the class of vehicle available in multiple grades. It can be used as a carrier in a large variety of formulations such as immediate release, sustain release, binder, stabilizer, solubility, and bioavailability enhancer, etc. Hence the review presented in this paper can be used as a ready source for researchers using kollidon in their formulations.

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