RESEARCH ARTICLE

Formulation and Evaluation of Immediate Release Tablets of Antimalarial Drug Hydroxychloroquine

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ABSTRACT

The goal of the study was to develop and evaluate an immediate-release antimalarial tablet formulation for the effective management of malaria, an antimalarial drug as an active pharmaceutical ingredient using excipients. Appropriate pharmaceutical products and evaluate their properties in relation to the innovative product. The study was to develop an antimalarial formulation with *in-vitro* solubility properties equivalent to or better than the improved formulation. Therefore, an orally administered immediate-release tablet with a robust and reproducible formulation technique was developed. According to the study, the number of F3 definitions decreased the most and F8 had the most important medicinal properties. At 20 minutes, F4 appeared to lead the first high decay rate (98. 56%), followed closely by F5 (93.48%). The expansion of F1, F2 and F3 shows high decay rates at this time. Based on this information, one can analyze and compare the decay profiles of unmistakable definitions. Things such as composition, excipients used, and manufacturing geometry can influence degradation behavior, and this information may be necessary to optimize concentrations of substances of interest for drug delivery. It is then concluded that the definition number F5 may be an optimized detail.

Keywords: Immediate release tablet, Hydroxychloroquine sulphate, Direct compression, Malerial drug.

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INTRODUCTION

At now, the pharmaceutical industry's preferred method of medication delivery is oral administration because it is the most cost-effective, patient-friendly, and safest option. A drug's solubility behavior, together with its permeability, is an important factor in determining its oral bioavailability. Some examples that readily come to mind are digoxin, phenytoin, sulphathiazole, chloramphenicol, and griseofulvin. The solubility and permeability of a medicine are the primary factors that determine its oral bioavailability.[1]

The medicine in immediate-release tablets dissolves quickly after dissolving in the mouth. To achieve immediate release, a pharmaceutically acceptable diluent or carrier can be used. A new alternative to traditional oral dosing forms is the immediate-release formulation. The accelerated rate of dissolution causes immediate-release dose forms to disintegrate shortly after delivery.[2]

Extending product life cycles, creating opportunities, and penetrating new markets are all goals of the current research and development of innovative medication delivery systems. Tablets are the most often used dosage form due to their portability, ease of production, and the fact that they can be self-administered. This is especially true in cases where a faster beginning of action is needed than with traditional treatment methods.[3]

About a third of patients require a medicine's therapeutic effects immediately, which causes them to not take their medication as prescribed, which lowers the efficacy of traditional pharmacological therapy. As a result, instant-release dosage forms have evolved as a substitute to traditional oral formulations, providing benefits of both ease of administration and convenience of administration in one convenient package.[4]

It is possible to die from malaria. *Plasmodium vivax, P. oval, P. malaria,* and *P. falciparum* are the four species of malaria. Mosquitoes that are infected transmit the *Plasmodium* parasite. The parasite is delivered into your circulation when this mosquito bites you. Parasites, once inside a host, will make their way to the liver to develop into adults. The adult parasites infect red blood cells after a few days of swimming into the bloodstream.[5]

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The parasites within the RBCs grow within 48 to 72 hours, leading to the infection cells bursting. The parasites still infect red blood cells, thus, symptoms come and go in cycles of two or three days. The more severe form of malaria caused by *P. falciparum* increases the chance of death for people who develop it. Another way for an infected mother to transmit the sickness to her kid is after birth.[6]

The medical term for this is congenital malaria. The parasites that cause malaria are most commonly found in warm, tropical, and subtropical regions. Travelers visiting malaria-stricken regions are at increased risk of contracting the disease[7]

MATERIAL AND METHOD

Ingredients like sodium starch glycolate, Carboxy-methylcellulose (CMC), sodium bicarbonate, MCC, Kyron 314, crosspovidone, and aerosil are procured from the Loba Chemical having vendor Arahant Invo-chem, Pvt, Ltd. PVPK 30, lactose monohydrate, magnesium stearate, and mannitol, Procure form the Mark chemical. The active ingredient, hydroxychloroquine sulphate has comes as a gift sample from Alkem Pharmaceuticals.

Preformulation Study

Identification of drug

- *Melting point determination*

It was done by capillary rise method and then verified to see if it matches the reported values.[8]

- *UV method*

Transfer 45 mg of hydroxychloroquine sulfate standard into a 50 mL volumetric flask after carefully weighing it. After adding 30 mL of diluent, sonicate it until it dissolves. Then, add enough diluent to bring the volume up to the mark, and stir well. Further, add diluent to 3 mL of standard stock solution until you get 200 mL. Hydroxychloroquine sulphate standard concentration: 13.5 ppm.[9]

- *Fourier transform infrared spectroscopy study*

To determine the API, an fourier transform infrared (FT-IR) analysis was performed. Scanning was performed on the samples within the 400 to 4000 cm^{-1} range.[10]

- *Solubility study*

The drug's solubility was tested in a variety of solvent systems.[11]

Formulation of Immediate Release Tablet

General procedure for tablet formulation

- *Dispensing and sifting*

All intragranular ingredients were weighed as per the required quantities then it sifted through ASTM #40 mesh.

- *Dry mixing*

Materials were mixed together manually for 5 minutes.

- *Lubrication*

Blend from dry mixing with magnesium stearate (#60 passed) manually for 5 minutes.

- *Compression*

Compression was done by 11.5 x 5.5 mm oval-shaped punch.[12] The formula is represented in Table 1.

Pre-compression Parameters

Angle of repose (Ø)

Using Ø, one can determine frictional force within a loose powder or grains.

$$Ø = \tan^{-1} (h/r)$$

Where,
Ø = height of pile
r = radius of the base of the pile

Under the influence of gravity, a test sample was allowed to flow freely through an aperture in a fully-filled funnel. The flowability of the granules was evaluated by taking the area of the pile from the cone created on a graph sheet. We also measured the pile's height.[13]

Bulk density

The tablet mixes and naproxen were tested for their loose and tapped bulk densities using a bulk density apparatus. In order to remove any possible clumps, the pure medication was run through a #18 sieve. The medication or polymers, each weighing 5, or 25 g, were measured out in a 100 mL graduated cylinder. We noticed the first volume. To start, a distance of 14 ± 2 mm was used to tap the cylinder 200 times. Accurately measuring the tapped volume was done using a graduated cylinder. There were an additional two hundred tappings. To the nearest graded unit, the tapped volume was once again determined. Tablet powder mixtures underwent an identical procedure. According to this formula, the LBD & TBD were determined in g/mL.[14]

Compressibility index (Carr's Index)

We used Carr's compressibility index to find the granules' compressibility index. The powders are graded according to Carr's Index and Hausner's ratio for their flow qualities.[15]

$$\text{Carr's Index} = 100\times (\text{TBD} - \text{LBD}) \div \text{TBD}$$

Hausner ratio

$$\text{Hausner ratio} = \text{TBD} / \text{LBD}$$

Evaluation of Tablet (Post-Compression Parameters)

Weight variation test

Both the individual and total weights of twenty pills were recorded. By adding up the weight of every tablet, we were able to get an average. We compared the average weight to the individual weights. The allowable range for weight variation percentages is within ±7.5%. There were 150 mg of active ingredient in the final tablet. The following Table 2 shows the %variation for tablet weight uniformity according to IP limitations.

There will be under-or over-medication if the weight of the tablet changes for whatever reason. Hence, it is important that the weight of each pill in each batch be consistent. Given that

Table 1: Formulation table containing various trails

Excipient	*Formulation (mg)*				
	F1	*F2*	*F3*	*F4*	*F5*
Hydroxychloroquine sulphate	200.0	200.0	200.0	200.0	200.0
Sodium starch glycolate	15	20	--	--	15
CMC	--	--	15	20	15
Sodium bicarbonate	10	10	10	10	10
MCC	15	15	15	15	15
Kyron 314	6	6	6	6	6
Crosspovidone	8	8	8	8	8
Aerosil	4	4	4	4	4
PVPK 30	8	8	8	8	8
Lactose monohydrate	35	35	35	35	35
Magnesium stearate	4	4	4	4	4
Mannitol	Q.S. to 300 mg				

the tablet contains 200 mg, any deviation from the IP permitted maximum of 7.5% is acceptable.

Upper limit –Average weight / Average weight × 100

Thickness

It is possible to tell how strong a tablet is to withstand compression forces by looking at its thickness. A digital caliper was utilized to determine the thickness of tablets.[16]

Hardness test

The power needed to break a tablet across its diameter is known as its hardness or its geometric crushing strength. The tablet needs to be able to withstand mechanical stress when being handled and transported. Different manufacturers and types of tablets have varying degrees of hardness. A Monsanto tester was used. The "hardness factor," which is the mean of the six findings, was calculated and published. The force was expressed as a kilogram per square centimetre.[17] The correct density is 4 kg/cm^3.

Friability test

The decrease of tablet weight in the container or package as a result of surface particle removal is called friability. The tablets' resilience to processing, handling, shipping, and shipment shocks is checked by conducting this in-process quality control test. A friability limit of 1% is permissible. Roche friabilator (Electrolab, Mumbai) was used. It was subjected the tablets to rolling, which caused them to tumble six inches within the chamber. There was a 25 rpm rotation speed. The tablets were removed from the friability after 100 rotations, which lasted for 4 minutes and weighed again as a group.[18]

$$\% \text{ Friability} = \frac{W1}{W1 - W2} \times 100$$

Where, W1 = Initial weight
W2 =Final weight

Drug content

The drug content was analyzed using a UV spectrophotometer at 232 nm with phosphate buffer pH 6.8 as the blank. Five pills were crushed and weighed to get a powder equivalent to 20 mg of naproxen. A suitable quantity of buffer was then added to the dissolved powder. The solution was filtered to make it appropriately diluted. Each batch was tested three times, and the average was determined.[19]

Table 2: Official limits of weight variation

USP standards	*Max.%difference allowed*	*B.P./I.P. Standards*
130 mg or less	10	84 mg or less
130–324 mg	7.5	84–250 mg
More than 325	5	More than 250 mg

B.P. = British Pharmacopoeia and I.P. = Indian Pharmacopoeia.

Disintegration studies

Another common use for the disintegration test is quick-dissolving tablets. Using the USP disintegration test device, the disintegration time is determined. For the disintegration test, six pills are utilized per batch. The disintegration test is carried out in 900 mL of artificial saliva fluid with a pH of 6.8 at a temperature of 37 ± 0.5°C and a flow rate of 30 ± 2 cycles per minute.[20]

Dissolution studies

We used the USP paddle method to dissolve all of the tablets, both those we made and those we bought, in 900 cc of buffer solution (pH 6.8) at 37 + 0.5° for our *in-vitro* dissolution tests. Spectrophotometric measurements were taken at 232 nm after 5 mL of the sample was withdrawn from the dissolving liquid at the prearranged regular intervals and passed through the Whatman filter paper. The dissolution medium was retained constant by adding an equal volume of freshly prepared medium that had been preheated to 37°C after each sample (Table 3). The next step was to provide a visual representation of the total percentage of drug release.[21]

RESULTS & DISCUSSION

Determination of Solubility

As per solubility analysis, naproxen was found to be freely soluble in ethanol and DMSO but slightly soluble in chloroform, which is shown in Table 4.

Determination of Melting Point

With the help of Thiele's tube apparatus, the determination of melting point take place was found to be 238℃ (Table 5).

UV analysis of AP

The spectrum analysis of naproxen reveals that its maximum wavelength is 220 nm. R2=0.9994 was the regression value for API (Table 6, Figure 1).

FTIR Spectroscopy Study

The molecular groups included in API were identified by the absorption bands it displayed. If there are no clearly visible, uncountable peaks and absorption bands that match the functional groups in the API structure, then the medication sample is pure (Tables 7, and 8, Figures 2 and 3).

Table 3 : Dissolution protocol

Parameter	*Specifications*
Dissolution apparatus	USP type 11/1P type 1
Dissolution medium	Phosphate buffer pH 6.8
Sample withdrawal at time intervals	0, 5, 10, 15, 20 minutes
Temperature	37 ± 0.50°C
RPM	50
The volume of the dissolution medium	900 mL
Volume withdrawal and replaced	5 mL
λ_{max}	220 nm

Table 4 : Solubility of naproxen in various solvent

Solution	*Absorbance*
Ethanol	3.4518
DMSO	2.8466
Water	0.3748

Table 5 : Melting point of naproxen

Drug	*Reference MP (°C)*	*Observed MP (°C)*	*Final MP (°C)*
Naproxen	240	238 239 238	238

Table 6: Concentration and absorbance values of API (λ_{max} 220 nm)

Concentration (µg/mL)	*Absorbance*
2	0.073
4	0.136
6	0.216
8	0.282
10	0.365

Table 7: Ranges of the functional groups present in I.R API

Functional groups	*Observed ranges (cm^{-1})*	*Standard ranges (cm^{-1})*
N-H stretch	3468.4	3550–3400
O-H stretch	3244.8	3300–3000
C-H stretch	2815.02	2900–2750
C-N stretch	1016.84	1100–950

Table 8 : Interpretation of IR spectra physical mixture of API and excipients

Functional group	*Peaks*	
	Pure drug	*Physical mixture*
N-H stretch	√	√
O-H stretch	√	√
C-H stretch	√	√
C=O stretch	√	√
C-N stretch	√	√

Table 9: Organoleptic parameters observations of various formulation

Formulations	*Properties*		
	Color	*Odor*	*Thickness (mm)*
F1	White	Odorless	4.0
F2	White	Odorless	3.9
F3	White	Odorless	4.0
F4	White	Odorless	4.0
F5	White	Odorless	4.0

Table 10 : Weight of each tablet & weight variation of each batch of tablet.

Formulation number	*Formulations*				
	F1	*F2*	*F3*	*F4*	*F5*
T1	300	300	300	300	300
T2	300	300	300	300	300
T3	302	300	300	300	300
T4	298	300	300	301	302
T5	301	300	300	298	300
T6	303	300	300	305	300
T7	300	305	298	297	298
T8	300	305	298	297	298
T9	300	305	298	300	300
T10	300	299	298	300	300
T11	300	299	300	300	300
T12	300	298	300	300	300
T13	301	300	298	300	300
T14	302	300	300	300	300
T15	304	298	300	300	300
T16	300	299	300	300	300
T17	300	300	298	299	298
T18	300	300	300	298	300
T19	300	300	298	300	300
T20	299	300	298	300	300
Total weight (mg)	6010	6008	5984	5995	5996
Average weight	300.5	300.4	299.2	299.75	299.8
Upper limit (mg)	304	305	300	305	302
Weight variation (%)	1.1	1.53	0.26	1.75	0.75

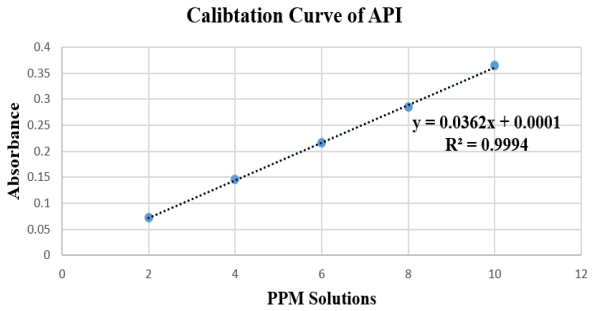

Figure 1: The graph contain the calibration of API

Post-Compression Parameter

Organoleptic properties

The organoleptic studies were reported in Table 9.

Weight variation

Each of the 20 pills has its weight recorded, and then the digital balance is used to weigh all twenty tablets simultaneously. After that, the tablet is used to find the average weight. This method is considered satisfactory by IP for determining the homogeneity of medication content. Hence we see that formulation number formulation number F3 (0.26%) has very less while formulation number F4 (1.75%) has the highest weight variation, which is shown in the graph (Table 10, Figure 4).

Tablet hardness

The tensile strength of a tablet is measured in kilograms per square centimeter. A tablet's crushing load is the amount of force needed to compress it in half. The Pfizer hardness tester, a tablet hardness tester, was used for the measurement (Table 11).

According to the observation of the table and the graph, the formulation number F3 (3.82 Kg/cm^2) has high hardness & F4 (1.6 Kg/cm^2) has low hardness (Figure 5).

Friability

The friability of tablets varies between 1.25 to 0.21% which is shown in the graph (Table 12, Figure 6).

Disintegration time

All the batches of fast-dissolving tablets for each formulation and found. Formulation number F3 has the highest DT & Formulation number F4 has the lowest DT (Table 13, Figure 7).

Drug content

As per the chart & graphical representation, formulation number F3 has the lowest & F8 has the highest drug content (Table 14, Figure 8).

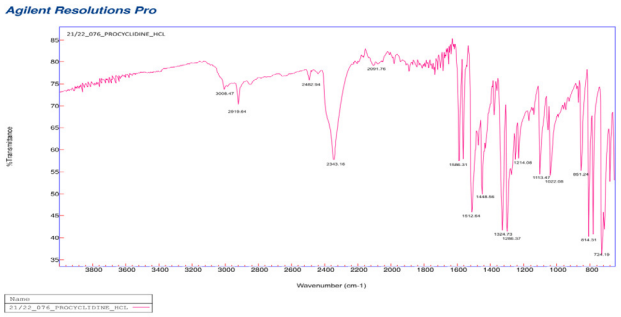

Figure 2 : Graphical representation of API

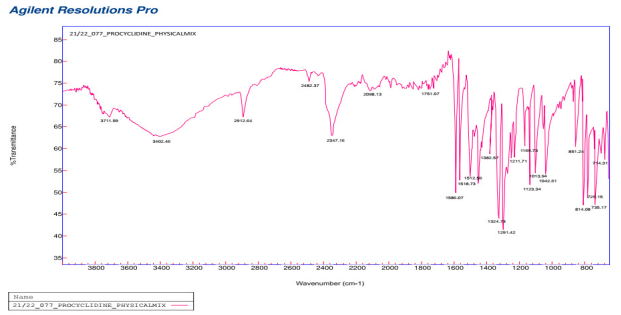

Figure 3: Graphical representation of API with tablet blend

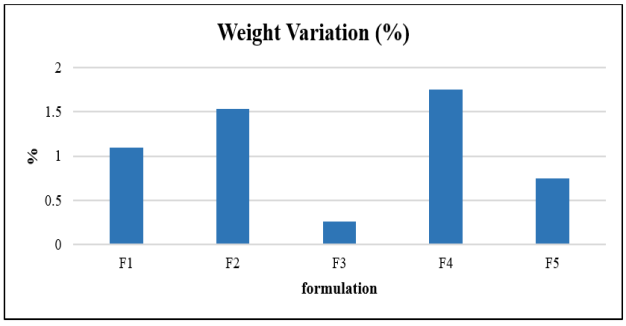

Figure 4 : Graphical representation of weight variation

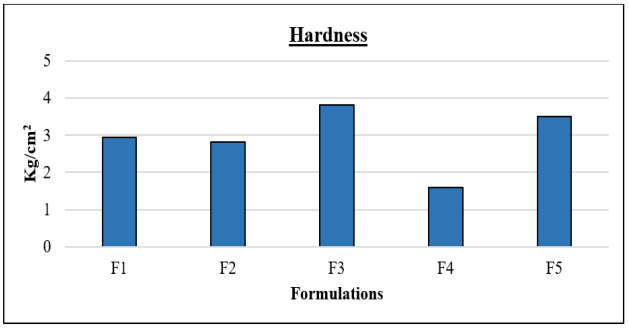

Figure 5 : Graphical representation of hardness

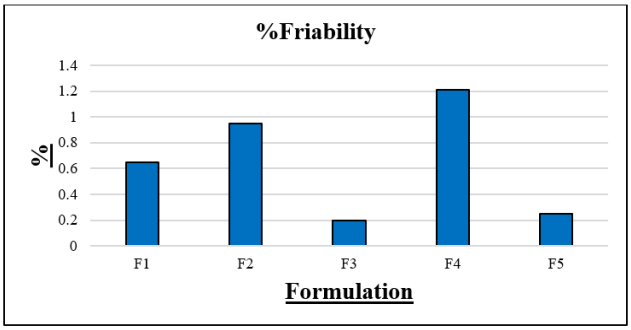

Figure 6 : Graphical representation of friability

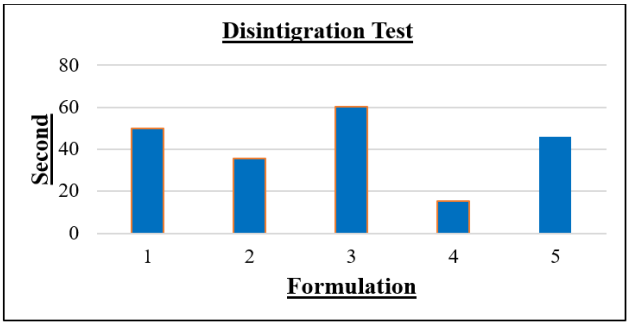

Figure 7 : Graphical representation of disintegration time

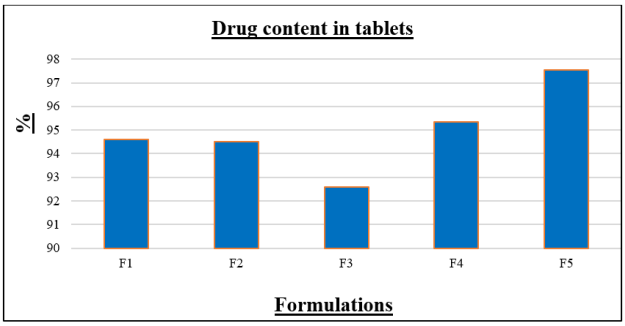

Figure 8: Drug contents

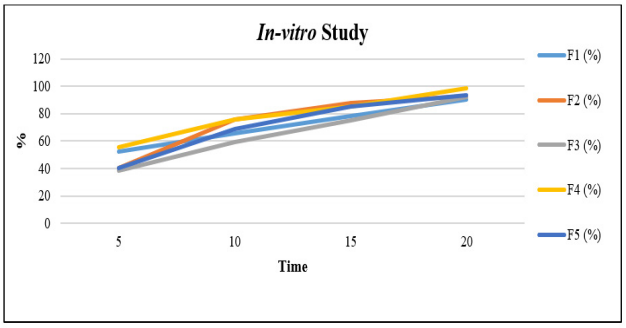

Figure 9 : Graphical presentation of *in-vitro* study

Table 11: The observation of the hardness evaluation

Formulation number	*Hardness of tablet*
F1	2.95
F2	2.82
F3	3.82
F4	1.6
F5	3.5

Table 12 : Friability of different formulation

Formulation number	*%Friability*
F1	0.65
F2	0.95
F3	0.20
F4	1.21
F5	0.25

Table 13: Disintegration time of different formulation

Formulation number	*Time of disintegration of tablet (sec)*		
	C1	*C2*	*C3*
F1	50.1	50.1	50.1
F2	45.6	45.6	35.6
F3	60.3	54.65	60.3
F4	15.5	15.5	15.5
F5	45.9	45.9	45.8

Table 14 : Drug content of various formulations.

Formulation number	*%Drug content*
F1	94.60
F2	94.52
F3	92.60
F4	95.36
F5	97.56

Table 15: *In-vitro* dissolution study

Time	*F1*	*F2*	*F3*	*F4*	*F5*
(min)	(%)	(%)	(%)	(%)	(%)
5	52.52	40.5	38.37	55.65	40.35
10	65.8	75.6	59.44	75.65	68.58
15	78.1	87.6	75.46	85.62	85.51
20	90.5	92.65	92.08	98.56	93.48

In-vitro dissolution study

At 20 minutes, F4 showed the highest dissolution rate (98.56%), followed closely by F5 (93.48%). F1, F2, and F3 also exhibited high dissolution rates at this time point. Based on this data, one can analyze and compare the dissolution profiles of different formulations. Factors such as formulation composition, excipients used, and manufacturing processes can influence dissolution behavior, and this data can be crucial for optimizing formulations for effective drug delivery (Table 15, Figure 9).

In weight assortment, we see that definition number F3 (0.26%) has outstandingly less, while definition number F4 (1.75%) has the most essential weight assortment, which is shown inside the chart. The friability of tablets shifts between 1.25 to 0.21%. At 20 minutes, F4 showed up the foremost lifted crumbling rate (98.56%), followed closely by F5 (93.48%). F1, F2, and F3 in addition, appeared tall crumbling rates at this time point.

CONCLUSION

Based on this data, one can analyze and compare the crumbling profiles of unmistakable definitions. Components such as enumerating composition, excipients utilized, and manufacturing shapes can affect crumbling behavior, and this data can be urgent for optimizing points of interest for compelling cure transport. Hence concluded, that formulation number F5 is an optimized formulation.

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