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Review Article

LIQUISOLID TECHNIQUE: A NOVEL APPROACH FOR DOSAGE FORM DESIGN

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ABSTRACT

The liquisolid technique is a novel approach for delivery of drugs through the oral route. This technique is suitable for poorly soluble or water insoluble drugs, highly permeable drugs (BCS Class II drugs) and also for immediate or sustained release formulations. It is a novel "Powder Solution Technology" that involves absorption and adsorption efficiencies, making use of liquid medications, drug suspensions admixed with suitable carriers, coating materials and formulated into free flowing, dry looking, non-adherent and compressible powder forms. The design of liquisolid systems are mainly intended for enhancement of solubility, dissolution rate and bioavailability of poorly water-soluble and highly lipophilic drugs. Improvement in bioavailability may be due to increased surface area, increased aqueous solubility and increased the wettability of the drug. Liquisolid technique also has the potential to be optimized for the reduction of drug dissolution rate and thereby production of sustained release systems. Overall, liquisolid technique is a most promising and novel technique for enhancing the dissolution and bioavailability of poorly water soluble drugs and sustaining drug release from tablet matrices. The current review mainly focuses on theory and applicability of liquisolid compact technique towards solubility or bioavailability enhancement. Different carriers, solvents and coating materials employed are elucidated. Literature reports on the applicability of liquisolid compact techniques over a wide range of pharmaceutical formulations are also explicated.

Keywords: Lipophilic, Bioavailability, Wettability, Carrier, Sustaining

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INTRODUCTION

Out of the numerous challenges in the design of pharmaceutical dosage forms, the most important is the solubility enhancement of poorly water-soluble drugs and improvement of bioavailability [1].

In recent years, the number of drug candidate has increased. However, most of these drugs are highly lipophilic and poorly water-soluble about 40% of the newly developed drugs and nearly 60% of the synthesised chemical entities suffer from solubility issues [2, 3].

Table 1: Descriptive terms for solubility according to Indian pharmacopoeia [4]

S. No.	Descriptive terms	Parts of solvent required to dissolve one part of solute (ml)
1	Very soluble	Less than 1
2	Freely soluble	More than 1 but less than 10
3	Soluble	More than 10 but less than 30
4	Sparingly soluble	More than 30 but less than 100
5	Slightly soluble	More than 100 but less than1000
6	Very slightly soluble	More than 1000 but less than 10,000
7	Insoluble	More than 10,000

Those belonging to the BCS class II and IV, dissolve poorly, slowly, and irregularly and hence possess serious delivery challenges like the incomplete release of drug from the dosage form, poor bioavailability of drug and high inter-patient variability [5].

Table 2: Biopharmaceutical classification system [5]

S. No.	BCS class	Solubility	Permeability	Examples
1	I	High	High	Metoprolol, Diltiazem, Verapamil, Propranolol,
2	II	Low	High	Danazol, Nifedipine, Ketoprofen, Naproxen,
3	III	High	Low	Atenolol, Captopril Ranitidine, Acyclovir
4	IV	Low	Low	Taxol, Furosemide.

Techniques for solubility enhancement

Many approaches have been developed for enhancement of solubility of poorly water-soluble and lipohilic drugs. Micronization technique is the most commonly used approach to improve drug solubility of poorly soluble drugs due to an increase in surface area. Other approaches, such as inclusion complexes, microencapsulation, and preparation of self-nanoemulsions and solid lipid nanoparticles have also been studied for dissolution enhancement of poorly water-soluble drugs [2].

Liquisolid compact technique

The liquisolid technique is a novel and most promising technique for improving the dissolution rate of poorly water-soluble drugs. In this technique with the use of carrier and coating materials the liquid form of drug converted into dry looking, non-adherent, free flowing, and directly compressible powder. In liquisolid system, the liquid portion is a drug suspension, liquid drug, or drug solution made in suitable non-volatile liquid vehicles [6, 7].

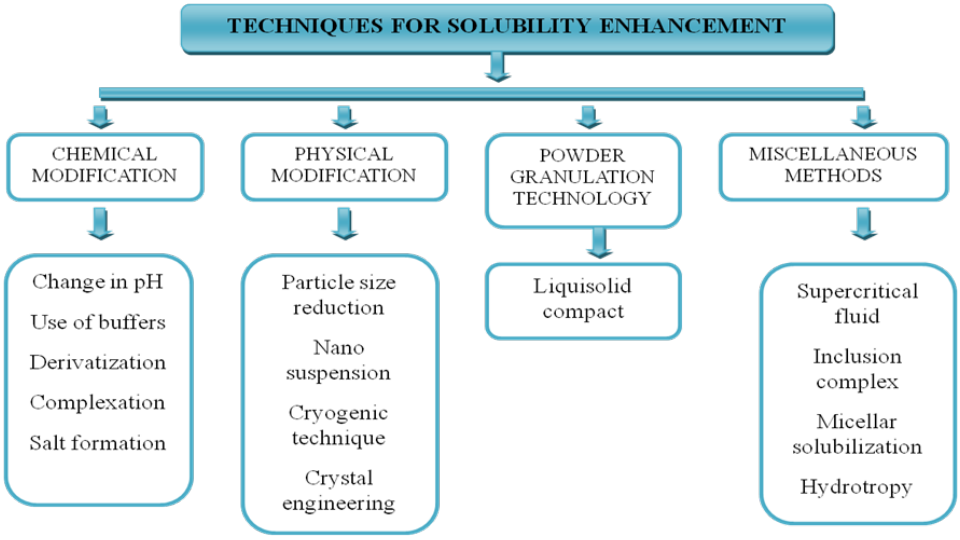

Fig. 1: Solubility enhancement techniques [2]

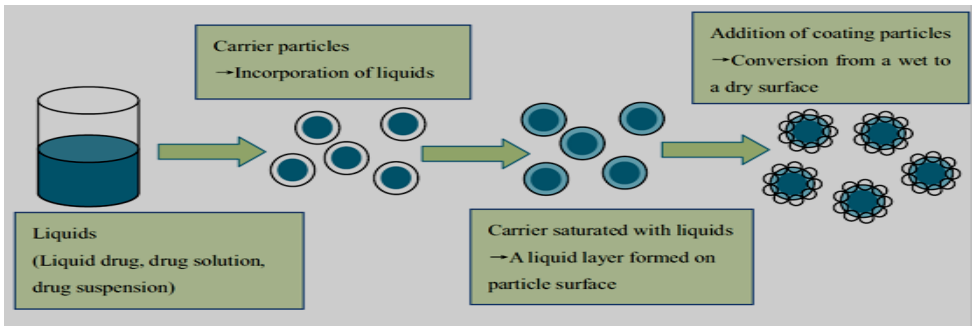

Fig. 2: Liquisolid compact formation [6, 7]

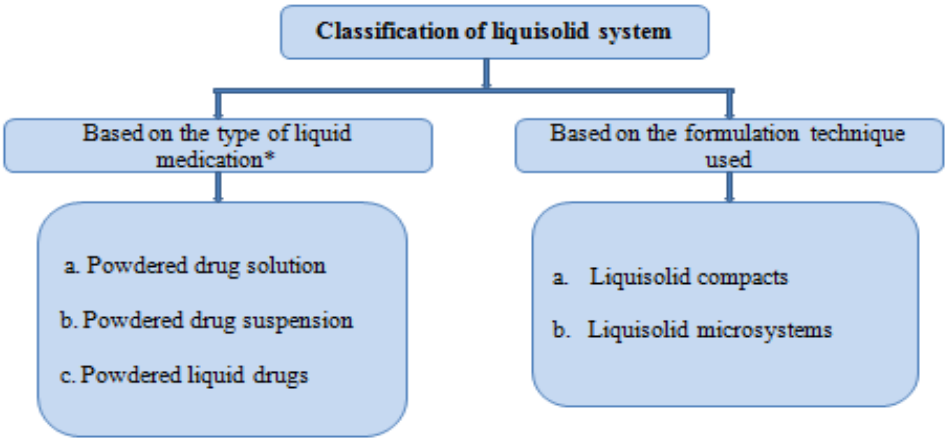

Fig. 3: Classification of liquisolid system [7, 8]

*Powdered drug solution, suspension, the liquid drug is produced from the conversion of drug solutions or drug suspensions, and formulation of liquid drugs into liquisolid systems.

Theory of liquisolid system [2, 9-11]

For the production of liquisolid systems amounts of powder excipients required is calculated by using a mathematical approach developed by Spireas. This approach is depends on the flowable (Ø-value) and compressible (φ-number) liquid retention potential introducing constants for each powder/liquid combination.

The φ-number of a powder is defined as the maximum amount of non-volatile liquid the powder can retain inside its bulk while maintaining acceptable compatibility resulting in compacts of sufficient hardness during compression. It can be measured as the maximum crushing strength of one-gram tablet compacted at sufficiently high compression forces.

The Ø-value of a powder is defined as the maximum amount of a given non-volatile liquid that can be retained inside its bulk while maintaining an acceptable flowability.

The liquid load factor that ensures acceptable flowability ($Ø_{Lf}$) can be determined by:

$$Lf = Ø + φ(1/R)$$

Where, Ø and φ are the Ø-values of the carrier and coating material, respectively.

Depending on the excipient ratio (R) of the powder substrate an acceptably flowing and compressible liquisolid system can be obtained only if a maximum liquid load on the carrier material is not exceeded.

$$R = Q/q$$

R represents the ratio between the weights of the carrier (Q) and the coating (q) material present in the formulation.

By using the following equation we can measure the quantities of carriers (Q_0) and coating (q_0) materials are required to convert liquid formulation (W) into acceptably flowing and directly compressible powder.

$$Q_0 = W/L_0$$

$$q_0 = Q_0/R$$

Table 3: Ø-values and *φ*-values of different carrier and coating materials [12]

S. No.	Powder excipients	Ø value		*φ* value	
		Propylene glycol	PEG 400	Propylene glycol	PEG 400
1	Avicel PH102	0.16	0.005	0.224	0.242
2	Avicel PH200	0.26	0.02	0.209	0.232
3	Cab-O-Sil M5 with Avicel PH 102	3.31	3.26	0.560	0.653
4	Cab-O-Sil M5 with Avicel PH 200	2.56	2.44	0.712	0.717

Enhanced drug release mechanism from liquisolid systems

Three main mechanisms are involved for enhancement of drug release from liquisolid systems are as follows

Increased drug surface area

In liquisolid system the surface area of drug available for drug release is much greater than that of drug particles within directly compressed tablets because the drug present in the liquisolid system is completely dissolved in the liquid vehicle and present in the powder substrate still in a solubilized, molecularly dispersed state [9].

Consequently, with increasing drug content, the solubility limit also increases and thus, increasing the fraction of undissolved drug in the liquid vehicle and thus, the release rate decreases. In the liquid solid formulation, the release rate of the drug is directly proportional to the fraction of the molecularly dispersed drug (FM). Spireas defined FM as the ratio of the drug solubility (Sd) and the actual drug concentration (Cd) in the liquid vehicle [13].

$$FM = Sd/Cd$$

Where FM = 1 Sd ≥ Cd

Fig. 4: Increased drug surface area [13]

Increased aqueous solubility of the drug

The solubility of the drug may be increased with liquisolid system. In fact, the small amount of the liquid vehicle in a liquisolid compact is not sufficient to increase the overall solubility of the drug in the aqueous dissolution medium. If the small amount of liquid vehicle acts as a co-solvent in liquisolid system this less amount of vehicle is sufficient to increase the aqueous solubility of the poorly water soluble drug [14].

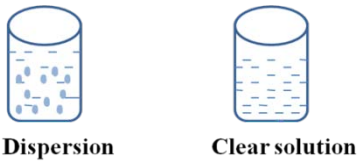

Fig. 5: Increased aqueous solubility of drug [14]

Increased wettability

The non-volatile solvent present in the liquisolid system provides wetting of drug particles by decreasing interfacial tension between tablet surface and dissolution medium so the contact angle of liquisolid system is lower when compared to the conventional formulation thus improved wettability [13].

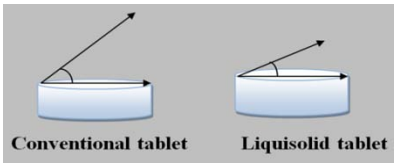

Fig. 6: Contact angle of conventional and liquisolid tablets [13]

Requirements for preparation of liquisolid systems

Drug candidates [15]

Drug substance with solubilities below 0.1 mg/ml face significant solubilization obstacles, and often even compounds with solubilities below 10 mg/ml present difficulties related to solubilization during formulation.

Table 4: Drugs used in liquisolid systems [15]

S. No.	Name of the drug	Use
1	Griseofulvin	Anti-fungal
2	Lovastatin	Hypertriglyceridemia
3	Felodipine	Anti-hypertension
4	Budesonide	Anti-asthmatic
5	Aceclofenac	NSAIDS
6	Carbamazepine	Anti-epileptic
7	Nevirapine	Anti-viral
8	Praziquantel	Anti-helmeted
9	Trimethoprim	Anti-biotic
10	Clofibrate	Antihyperlipidemic

Non-volatile solvent

Non-volatile solvents used in the liquisolid systems should be safe, water-miscible, inert, not highly viscous. The carriers and coating materials required to prepare the liquisolid system decreases with increase in the solubility of the drug in a non-volatile solvent [16].

Carrier materials

Carriers used in liquisolid systems should have a porous surface and high liquid absorption capacity. Specific surface area and liquid absorption capacity are the most important properties of carriers and these carriers incorporate large amount liquid in its structure [2, 16].

Coating materials

The coating material in liquisolid system should be a material possessing fine (0.01–5 μm in diameter) and highly absorptive particles, which contribute to covering the wet carrier particles and displaying a dry powder by adsorbing excess amount of liquid to ensure good flowability of created blend [5].

Table 5: Various non-volatile solvents used in liquisolid system [6]

S. No.	Non-volatile solvent	HLB value
1	Propylene glycol	2.5
2	Polyethylene glycol 200 monostearate	8
3	Polyethylene glycol 400 monostearate	11.5
4	Polysorbate 80	15
5	Capryol™ 90	5

Table 6: various types of carrier materials used in liquisolid system [2, 6]

S. No.	Carrier material	Specific surface area (m^2/g)
1	Microcrystalline cellulose	1.18
2	Lactose	0.35
3	Sorbitol	0.37
4	Starch	0.6
5	Fujicalin®	40
6	Neusilin®	300

Table 7: Various types of coating materials used in liquisolid system [6]

S. No.	Coating material	Composition	Specific surface area(m^2/g)
1	Cab-O-Sil®M5-P	Untreated fumed silica	220
2	Syloid®	Amorphous silicon dioxide	312
3	Aerosil®200	Hydrophilic fumed silica	200
4	Neusilin®	Amorphous aluminomagnesium metasilicate	44-250

Other additives

The disintegration of solid dosage forms noticeably influences drug release, Sodium starch glycolate is most commonly used disintegrant in the formulation of liquisolid tablets [1].

Polyvinylpyrrolidone (PVP) is another promising additive, which has the potential to incorporate a high amount of drug into liquisolid systems and minimizes the overall tablet weight.

There is another additive used in liquisolid systems–HPMC, which usually acts as a release retarding agent to sustain drug release from liquisolid tablet [8].

Advantages of liquisolid systems [11, 15, 17]

1. Liquisolid technique has the potential to formulate liquisolid tablets or capsules with pH-independent drug release pro files.

2. Enhanced bioavailability can be obtained in liquisolid technique.

3. Though the drug is in a tableted dosage form it is held in a solubilized liquid state, which increases drug wetting properties, drug dissolution rate and bioavailability.

4. Industrial production of liquisolid tablets or capsules is Possible.

5. Water insoluble drugs exhibit enhanced *in vivo* and *in-vitro* drug release profiles in the liquisolid system.

6. For the formulation of the liquisolid system, less excipients are required when compared to conventional formulations.

7. Increased surface area of drug exposed to dissolution medium.

8. By using hydrophobic carriers like Eudragit® RL and RS formulation of sustained release liquisolid tablets are possible.

9. Production cost is low when compared to soft gelatin capsules.

10. Liquisolid approach omits the process approaches like nanonisation, micronization techniques.

Disadvantages of liquisolid systems [18-20]

1. Liquisolid systems require high solubility of drug in non-volatile solvents.

2. High levels of carrier material and coating materials should be required in order to achieve acceptable flowability and compactibility for liquisolid powder formulation.

Liquisolid system is the problematic formulation of a high dose of poorly water soluble drugs (e. g., carbamazepine, budesonide).

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Disadvantages of liquisolid systems [18-20]

3. Liquisolid systems require high solubility of the drug in non-volatile solvents.

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5. Liquisolid system is the problematic formulation of a high dose of poorly water soluble drugs (e. g., carbamazepine, budesonide).

Applications of liquisolid systems [21-25]

1. Drug photostability in solid dosage forms is improved by liquisolid technique.

2. The rapid and prolonged release of drugs is obtained in liquisolid formulations.

3. The liquisolid technique is most efficiently used for water-insoluble solid drugs or liquid lipophilic drugs.

4. Liquisolid technique minimizes effect of pH variation on drug release.

Drug solubility, dissolution rate is enhanced in liquisolid technique.

Recent reports on liquisolid technique

Mustafa E *et al.* (2017) had designed orodispersible tablets of zolmitriptan by using liquisolid technique. Orodispersible tablets were prepared by using propylene glycol, avicel PH-102 and aerosil 200 as a non-volatile solvent, carrier material and coating material respectively and various types of super disintegrating agents such as croscarmellose sodium, sodium starch glycolate, and crospovidone to facilitate faster disintegration of the liquisolid compact.

The overall results showed that among the three super-disintegrants, crospovidone was the best super disintegrant showing the shortest disintegration time while loading factor of 0.125 was the best in the preparing of zolmitriptan liquidsolid orodispersible tablets [26].

Procedure for designing of liquisolid formulation

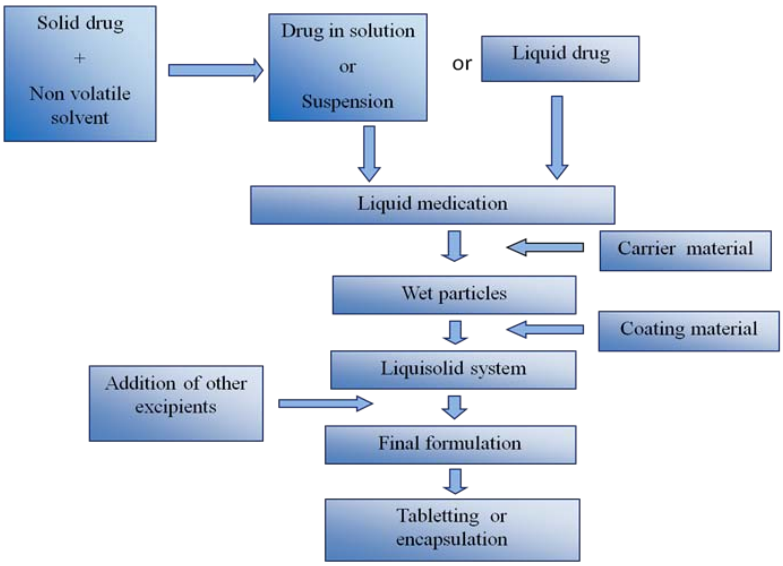

Fig. 7: General preparation procedure of liquisolid formulation [2]

Padmapreetha J *et al.* (2016) had formulated liquisolid compact to enhance the dissolution rate of leflunomide by using kolliphor EL, avicel PH 102, aerosol, and sodium starch glycolate as a non-volatile solvent, carrier, coating material and super disintegrant respectively. The results showed that during the first 10 min ($Q_{10\%}$) the optimized formulation released 73.39% of its content compared to 18.94 % of the conventional formulation. In conclusion, leflunomide dissolution rate can be enhancing to a greater extent by liquisolid technique [27].

Mowafaq MG *et al.* (2015) had prepared liquisolid compact for solubility enhancement of tenoxicam using tween 80 as a non-volatile liquid, avicel PH102 as a carrier, and aerosil 200 as a coating material. Liquisolid formulations containing various drug concentrations in liquid medication ranging from 10% to 35% w/w were prepared. Liquisolid formulations showed greater drug release rates than conventional and marketed tablets due to increasing surface area of the drug and wetting properties [28].

Hitesh J *et al.* (2014) had compared liquisolid and inclusion complexation techniques for dissolution rate enhancement of valsartan. This study was designed for screening of suitable non-volatile liquid solvent for the preparation of liquisolid compact such as tween 80, polyethyleneglycol 400 and propylene glycol by using the mathematical equation. The study was also aimed for enhancement of dissolution rate and comparison of liquisolid technique with inclusion complex of β-cyclodextrin. The liquisolid formulation showed highest dissolution rate compared with directly compressed tablet, pure drug, and formulation prepared by complexation technique [29].

Yesubabu B *et al.* (2014) had formulated fast disintegrating tablets of lamotrigine using different super disintegrating agents such as crospovidone, sodium starch glycolate. Various batches of liquisolid tablets were prepared. Formulations consisting of sodium starch glycolate were found to be fulfilling all the parameters satisfactorily

when compared with crospovidone. *In-vitro,* drug release studies showed that within 30 min almost 90% of the drug was released from all the formulations confirming enhancement of drug dissolution by liquisolid technique [30].

Ali N *et al.* (2008) had designed sustained release liquisolid compact of propranolol hydrochloride by dispersing the drug in polysorbate 80 as the non-volatile solvent. A binary mixture of Eudragit RL or RS were used as the carrier. Silica was added to the liquid medium as the coating material with continuous mixing in a mortar. Then the final mixture was compressed using the tablet punching machine.

The effect of drug concentration, loading factor, thermal treating and aging on drug release profiles of propranolol HCl from liquisolid compacts was investigated at two different pH values such as 1.2 and 6.8. In conclusion, propranolol HCl tablets prepared by liquisolid system showed greater retardation properties than conventional matrix tablets [31].

Table 8: Literature reports on formulations of liquisolid compact

S. No.	Drug	Non-volatile solvent	Carrier material	Coating material	Ref. No.
1	Budesonide	PEG 400	Avicel PH 102	Aerosil 200	19
2	Carvedilol	PEG 400	Avicel PH 101	Aerosil 200	32
3	Candesartan cilexetil	Tween 80	Avicel PH 102	Aerosil 200	33
4	Efavirenz	Propylene glycol	Avicel PH 102	Aerosil 200	34
5	Felodipine	PEG 400	Avicel PH 102	Aerosil 200	35
6	Gliclazide	Acrysol EL 135	Avicel PH 102 and Neusilin	Aerosil 200	36
7	Glyburide	PEG 400	Avicel PH 101 and 102	Aerosil 200	37
8	Hydrochlorothiazide	PEG 400+Water+Tween 60	Microcrystalline cellulose	Colloidal silicon dioxide	38
9	Ibuprofen	PEG 400	Avicel PH 101	Aerosil	39
10	Indomethacin	Glycerin	Micro crystalline cellulose	Silica	40
11	Naproxen	PEG 400, 200, 600, PG, Glycerin, Tween 80, Cremophor EL and Poloxamer 181	Microcrystalline cellulose and Dicalcium phosphate	Colloidal silica	12
12	Nateglinide	PEG 400	Avicel PH 102	Aerosil 200	41
13	Nifedipine	PEG 400, PG and Tween 80	Avicel PH 102	Silica gel powder	42
14	Olmesartan medoxomil	Acrysol EL 135	Avicel PH102, Fujicalin and Neusilin	Aerosil	43
15	Trimetazidine dihydrochloride	Tween 80	Avicel PH 102	Aerosil	44
16	Tramadol hydrochloride	Propylene glycol	Avicel PH 102	Aerosil 200	45

CONCLUSION

Enhancement of the solubility and dissolution rate of poorly water-soluble drugs is still a major challenge for pharmaceutical scientists. At the same time sustaining the drug release from dosage forms helps in a better and proper utilization of the drug. Both of these applications are major requisites for enhancement of drug bioavailability. Finally, from this review, it can be concluded that, among the various techniques involved for the drug bioavailability enhancement, liquisolid technology is one of the most promising approaches. It is found to be a multipotential and promising technology for dosage form development, because of the process simplicity, low economic inputs during production and possible industrial feasibility due to the good flow and compaction characteristics of liquisolid formulations.

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CONFLICTS OF INTERESTS

Declare none

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