



Short Communication

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ASU related Indian drug laws for hand sanitizers in the light of COVID-19

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ABSTRACT

There is a huge surge of demand for Hand sanitizers and other protective gear like N-95 masks and PPEs on account of the pandemic situation arising due to Covid-19. Hence apart from modern drug firms, Ayurveda, Siddha & Unani (ASU) manufacturing units also have the provision for preparation of hand sanitizers within the limits of drug laws. This short communication, discusses the ASU related legal aspects for the manufacture of alcohol based hand sanitizers.

Keywords: Covid-19, Hand sanitizers, Indian drugs law.

INTRODUCTION

A new novel Corona virus disease which had flu or influenza like symptoms became endemic and ultimately changes itself to pandemic status throughout the world at the beginning of the year of 2020. The epicenter of the disease is believed to be in Wuhan province of China [1]. It is believed to be zoonotic in nature during early spread, but quickly changes its course to human to human transmission within a short period of time.

It became a matter of international concern, when the Director-General of the World Health Organization on 30th January, 2020 declared a public health emergency and issued temporary recommendations [2].

WHO recommends of maintaining proper hand hygiene by cleaning hands with soap water for at least twenty seconds. It is the best way of personal hygiene to prevent the spread of the disease. There is certain situation where the use of water is limited or restricted like when we are travelling or in a region with scanty clean water resource. In those situation, in the case of unavailability of water, alcohol based hand sanitizers could be used to combat the disease.

For best compliance of hand hygiene, hand rubs could be available for the masses in the form of dispensers or through small bottle that are easy to carry and are for single person use.

WHO recommends alcohol containing hand sanitizers based on some important observations. Some of them are as follows:

1. Evidence-based, quick-acting and having broad-spectrum microbicidal action.
2. Low risk of evolving resistance to antimicrobial agents.
3. Easy to use in those areas with limited resources like unavailability of sinks, clean water, towel etc
4. Ability to execute improved compliance with hand hygiene by making the process quick and convenient
5. Economically feasible by lowering annual costs budget in the hand hygiene sector.

According to the WHO guidelines published on 5th May for local production of hand sanitizers, two formulas are mentioned [3].

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Formulation I

Serial no:	Ingredients with their final concentration in formulation	Process to prepare one liter hand sanitizer/rub
1.	Ethanol 80% v/v	Ethanol 96% v/v 833.3 ml, H ₂ O ₂ 3% 41.7 ml, glycerol 98% 14.5 ml. Volume make up is done upto 1000 ml with distilled water or water that has been boiled and cooled, and then followed by shaking
2.	Glycerol 1.45% v/v	
3.	Hydrogen peroxide (H ₂ O ₂) 0.125% v/v	

Formulation II

Serial no:	Ingredients with their final concentration in formulation	Process to prepare one liter hand sanitizer/rub
1.	Isopropyl alcohol 75% v/v	Isopropyl alcohol (with a purity of 99.8%) 751.5 ml, H ₂ O ₂ 3% 41.7 ml, glycerol 98% 14.5 ml. Volume make up is done upto 1000 ml with distilled water or water that has been boiled and cooled, and then followed by shaking.
2.	Glycerol 1.45% v/v	
3.	Hydrogen peroxide (H ₂ O ₂) 0.125% v/v	

Hand sanitizers are licensed under Drug & Cosmetics rule, 1945, and the standards are abided by the Second schedule of Drug & Cosmetics Act, 1940.

On 13th March, 2020, Indian Government has notified with an Order under the Essential Commodities Act to declare hand sanitizer as Essential Commodity up to 30th June, 2020 by amending the Schedule of the Essential Commodities Act, 1955. The decision would empower the governments to regulate production, quality and distribution of hand sanitizers and will eventually help to vigil and curb the overpricing and black marketing of hand sanitizers [4].

For easy availability of hand sanitizers to all the section of citizens, the Government also capped the retail price of hand sanitizers at Rs 100 per bottle of 200 ml via a circular as posted on 21st March [5].

Furthermore for expediting the licensing process for manufacturing of ASU based hand sanitizers, and immunity boosting health care products, Ayush Ministry came with a circular in 2nd April, 2020 [6].

Preparation of hand sanitizers through ASU laws

The inclusion of hand sanitizers in ISM related drugs can be approached by two approaches.

1) First Approach: WHO recommends Ethyl alcohol/ Isopropyl alcohol, H₂O₂ and Glycerol to be added to manufacture hand sanitizers. As an additive in the Drugs & Cosmetics rules, under Rule 169 (Permitted excipients), manufacturer can add excipients like additive, preservative, antioxidants, flavoring agents, chelating agents etc that are permitted in the Indian Pharmacopoeia (IP), Prevention of Food Adulteration Act, 1954 and Bureau of Indian Standard Act, 1986, with certain conditions applied.

Hence ASU manufacturers may add ethyl alcohol or Isopropyl alcohol and glycerol as excipients to manufacture hand sanitizers as they come under the category of pharmaceutical aids like humectant, solvent etc according to Indian Pharmacopoeia, 2010.

Though as a general rule, excipients are usually added in a minimalist concentration (alcohol based hand sanitizers demand high concentration of alcohol for effectiveness) and also rule 161 of D & C rules stated the labeling, packing and limit of alcohol where the maximum size of packing is 15 ml for classical formulation having high contents of alcohol as a base namely for Karpurasava, Ahiphenasava and Margamadasava. But the authors of this short communication come to the opinion that all the above mentioned three classical alcoholic preparations are for internal use and also excipients should be used in minimal concentration for drugs of internal use but hand sanitizers are for topical and external use, and also on the humanitarian context the pandemic situation arised due to Covid-19 needs adequate and surplus production of hand sanitizers.

But the authors of this short communication also thinks that, as H₂O₂ doesn't comes under the category of pharmaceutical aid, but comes under the category of antiseptic or deodorant according to I.P, 2010, hence its addition in ASU drugs is not appropriate according to ASU related Drug & Cosmetics laws or till further orders come into force.

2) Second Approach: Similarly, Alcohol can be added in the formulation as Other Active Ingredients without considering it as an Additive.

Asava and Arista are self generated alcohol in Ayurved. There are certain cases where 'Prasanna' which may be considered as a form of rectified spirit in classical alcoholic preparation in Ayurveda is added to the drug. The fermented liquor prepared by cooked rice, barley etc is known as Sura. The clear supernatant fluid of Sura is known as Prasanna. In some of the classical medicine of this group such as Karpurasava, Prasanna which is distilled alcohol from fermented solution is added to powdered drugs, kept for some time and then filtered. In accordance with the process given in Kadambari madya in Bhava prakash, Prasanna is prepared by Sastika (*Oryza sativa*) 1 part, Yavadhanya (*Hordeum vulgare*) 1 part, Haritaki (*Terminalia chebula*) 1 part, Guda (Jaggery) 1 part, Kadali (*Musa paradisiaca*) 10 Numbers.

Cooked Yavadhanya was mixed with Haritaki Kwath(decoction). The powdered Sastika was added and lastly followed by Guda and mashed banana. Then it is kept for fermentation. After fermentation the product is distilled by Vaka yantra or glass distillation apparatus to obtained Prasanna. Prasanna thus produced is used in the manufacture of Karpurasava.

Hand sanitizers will come under Patent or proprietary medicines and regarding patent or proprietary medicine in rule 158-B, Section 3(h) it is stated that all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of ASU medicines that specified in the First Schedule, but does not include a medicine which is administrated by parenteral route and also a formulation included in the

authoritative books. Hence Prasanna of appropriate concentration as an, 'Other active ingredient' could be used in the manufacture of hand sanitizers.

CONCLUSION

After capping the price of hand sanitizer and recent expediting the licensing process, the availability of hand sanitizer has markedly increased in Indian market which bridges the gap of supply and demand. Maintaining proper hand hygiene like using Hand sanitizers, washing hands, etc not only protect us from Covid-19 but also protect us from several other diseases. Manufacturing of ASU based hand sanitizers not only boost the overall prevention from the pandemic but also boost the ASU drug market potential in India.

REFERENCES

1. Paraskevis D, Kostaki EG, Magiorkinis G, Panayiotakopoulos G, Sourvinos G, Tsiodras S. Full-genome evolutionary analysis of the novel corona virus (2019- nCoV) rejects the hypothesis of emergence as a result of a recent recombination event. *Infect Genet Evol* 2020;79:104212.
2. World Health Organization. Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV).
3. WHO guidelines of local production of hand sanitizers https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf [cited on 8.6.20]
4. 'Govt brings masks and hand sanitizers under the Essential Commodities Act' as viewed from <https://pib.gov.in/PressReleaseDetailm.aspx?PRID=1606403> [cited on 10.6.20]
5. 'Govt caps prices of hand sanitizers, masks; States/UTs asked to maintain essential supplies' as viewed from <https://pib.gov.in/PressReleaselframePage.aspx?PRID=1607528> [cited on 10.6.20]
6. Ministry of Ayush Circular, as viewed from <https://www.ayush.gov.in/docs/124.pdf> [cited on 10.6.20]

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