Can Cow Urine Distillate be Used for Human Health Care? If so, what would be the Pharmaceutical Manufacturing Standards?

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Abstract

Cow Urine Distillate (CUD), is a modern pharmaceutical product with five US patents for use in cancer treatment and for other ailments. Many published papers in medical literature, including those in MEDLINE, document many therapeutic properties of CUD. Unfortunately, none of these papers have any information on minimum quality standards for CUD manufacturing: for use in pharmaceutical products for human health care. There also does not seem to exist any published paper discussing pharmaceutical quality standards for manufacturing CUD. Some possible pharmaceutical manufacturing quality standards have been suggested in this paper to start a discussion.

Keywords: Cow urine distillate; CUD; Therapeutic properties of Cow Urine Distillate; Cow Urine Distillate utility in cancer treatment; Bio enhancement of antibiotics; Pharmaceutical manufacturing standards for Cow Urine Distillate.

Introduction

Why investigate cow urine distillate?

Across many parts of the Asian continent, the Cow is venerated, as it is believed to create many usable products for human consumption. Cow Urine has been traditionally revered for its supposed pharmaceutical properties. This belief has been "modernised"; with the distillation of cow urine: and its packaging and distribution in modern markets. This paper attempts to critically examine the pharmaceutical uses of cow urine distillate. Reports of successful use of Cow Urine Distillate (CUD) have opened

be integrated into mainstream western medicine[1]. Other reports however have questioned whether CUD is the real thing; or is this a case of unbridled Hindu fundamentalist enthusiasm fuelling yet another bubble[2]?

the flood gate of possibilities; that CUD can

Pharmacological patents for CUD

CUD has been patented for several pharmaceutical uses. CUD has been claimed to enhance the antimicrobial effect of an antibiotic. The antibiotic could be an antifungal agent (quinolene, fluoroquinolone) and the antifungal agents could be azoles, clotrimazole, mystatin, or amphotericin. Claims have been made for bio enhancing antibiotics, which target tuberculosis, like isoniazid, pyrazinamide, and ethambutal[3]. A bioactive fraction from CUD has been claimed as a bioenhancer of anti infective, anti cancer agents and nutrients. Apart from claims of the bio active fraction bio enhancing antibiotics which target tuberculosis; claims were also made of bio enhancement of anticancer agents from the group consisting of Paclitaxol (Taxol)[4,5]. Redistilled cow urine

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distillate (RCUD) has been claimed for protecting and/or repairing DNA from oxidative damages[6]. A news item claimed that Oxidative DNA damage is a leading cause of ageing, cancer and other diseases:- and that RCUD works against genotoxicity, a harmful action on a cell's genetic material. Further the RCUD was claimed to have been tested on a few cancer patients[7].

Clinical data on use of CUD in human health care

The electronic American medical research database MEDLINE has three papers on the possible pharmaceutical use of CUD. CUD decreased the parameters for liver toxicity in rats which had induced hepatotoxicity with carbon tetrarchloride[8]. Redistilled CUD significantly moderated the toxicity of known genotoxicants and clastigens, manganese dioxide, and hexavalent chromium. This particular effect was attributed to the anti oxidant property of RCUD[9]. Redistilled CUD significantly prevented the DNA damage induced by chemicals like hydrogen peroxide and Actinomycin D (anti tumour drug). Gas Chromatography showed that RCUD had total anti oxidant status of 2.6 mmol; contributed mainly by volatile fatty (1500mg/litre); which hypothesized to have caused the observed protective effects[10].

Raw cow urine the only raw material for conversion to CUD, itself has pharmaceutical properties. In Ayurveda, raw cow urine is used in processing aconite: a toxic alkolide, associated with a medical plants of the genus aconitum[11]. Raw cow urine has also been noted to enhancing effectiveness of cancer therapy: through enhancing immunocompetence, improving general health, prevent free radical formation, reducing apoptosis in lymphocytes, repairing DNA and acting as an anti ageing factor[12].

CUD as also raw cow urine has been established to have anti microbial/bacterial properties. CUD has been reported for antimicrobial activity; for bacteria, *Bacillus*

subtilis, Pseudomonas aeruginosa, Klebsiella pneumoniae and Salmonella typhi. At a concentration of 15 microlitres, CUD fared better then the Standard antibiotic disc Ampicillin (30mg/disc)[13].

When tested with the agar well diffusion method, raw cow urine reported significant zones of inhibition for; *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas fragi*, *Bacillus subtilis*, *Streptococcus agalactiae*, and *Proteus vulgaris*[14].

CUD has been demonstrated to control insect vectors. Laboratory experiments showed CUD to induce mortality in the larvae of the mosquito *Aedes aegypti:* which is stated to be responsible for arboviral diseases like dengue and chickunguyna[15].

Tests on lab rats have confirmed further pharmaceutical properties. CUD has been reported to have had analgesic effects - using the rat tail immersion method. CUD fared well in comparison with the chemical analgesic Diclofenac Sodium[16]. Anti bacterial property against E.Coli, was tested with albino rats who were orally administered E. coli: with mortality percentage and clinical symptoms being recorded on the 90th day. The group administered CUD seemed to have significantly lower mortality rates, then the control (no treatment)[17]. The anti diabetic effect of CUD was established administration of streptozotocin. CUD showed a statistically significant reduction of the elevated blood glucose, serum cholesterol and serum triglycerides levels when compared with the diabetic control. The diabetic animals treated with CUD also showed a significant increase in HDL levels and a gain in body weight when compared with the diabetic control. The CUD dose of 10.8 ml/kg body weight, nearly matched the effect of the standard drug Gibenclamide[18].

Pharmacological Manufacturing Standards for CUD

For incorporating the distillation of cow urine into pharmaceutical manufacturing, minimum standards need to be established for industrial manufacturing units. An internet search in medline, pharmacological databases and in google scholar did not seem to reveal a single paper on the pharmacological standards for manufacturing CUD. This seemed surprising, and perhaps indicates that not much research work has been done in the standardisation of cow urine distillate. We have considered this to be a significant gap in knowledge; and have made an attempt to establish the possible and minimum quality standards; for a product that is to be used in human health care. Also, without such quality standards, it is difficult to envisage how sufficient quantities of CUD can be produced in industrial manufacturing processes- if mainstream medicine starts to integrate the use of CUD into human health care.

The recent experience of setting up a cow urine distillate plant using "multi column distillation technology" in Uttarkashi (Uttarakhand state in India), seemed to further amplify the need for such quality standards.

to have designed the plant keeping the mind the requirements of distillation of water for parenteral solutions, and water for injection[19]. Raw cow urine has a different physical, chemical and biological composition than water? Hence the renewed urgency to start this discussion around possible quality standards, both for the input, raw cow urine and for the output, CUD. We do so in the context of pharmaceutical industrial manufacturing; with all the attendant regulatory and legal complexities.

We tested the sample of the raw cow urine and the manufactured output CUD, distilled from a single column distillation plant. The samples were taken on two separate days, with around a month's time interval between these two days, from Uttarkashi. These samples were tested in a chemical laboratory, exclusively used for testing the pharmaceutical quality standards of medicine. The tests were done immediately after receipt of the sampleso there would be around a month's difference

	Raw cow urine			Cow Urine Distillate			
Parameter	Raw cow urine literature	Mean	Standard deviation	Coefficient of Variation	Mean	Standard deviation	Coefficient of Variation
pН	8.25 ²⁰	8.38	0.08	0.95%	9.88	0.13	1.31%
Total Dissolved Solids (TDS) (%)	2.521	2.37	0.18	07.6%	0.47	0.40	85.10%
Hardness (in parts per million)	Not available	863	51	05.9%	4	4	100%
Specific Gravity	Not available	1.0134	0.0007	0.069%	0.9994	.0005	0.05%
Water (H ₂ O)(%)	95 21	95.38	0.47	0.49%	94.79	0.31	0.32%

Table 1: Analysis of Raw Cow Urine and Cow Urine Distillate

An internationally reputed engineering firm had been commissioned to design, erect and commission a new multi column distillate plant. The project objective was to increase efficiencies and capacities from the present single column cow urine distillation plant. However, the manual sent, along with the equipment, seemed to relate only to using multi column distillation for water as a raw material source. The manufacturer appeared

in the dates of the analysis of the two samples. The numerical values which came from the analysis is as under-

Analysis

A simple analysis would be look at the available data from a web search on cow urine parameters and compare with the test results. One should also note that only the pH value

of the literature can be affirmed to be coming from a published research paper. The values for TDS and Water percentage are from a blog, and hence needs to be treated with caution. The values for pH vary by 1.5%, that of TDS by 5% and that of water by 0.4%. It can be hence perhaps concluded that the cow urine samples seem to more or less match that of available values of the literature.

The next analysis would be to compare the parameter values of the raw cow urine and that of the distilled CUD. The difference seems to be significant in the case of pH, Total Dissolved Solids (TDS) and hardness; and lower in terms of specific gravity and water percentage. The increase in the pH values of the CUD is 18% more then cow urine: which seems to imply that there is a decline in power of hydrogen ions (H⁺) after distillation. There would be more hydroxy l ions then hydrogen ions after distillation.

In the case of TDS, the parameter values seemed to decline by around 83%; and for hardness, by a factor of around twenty times. This seems to reflect the effectiveness of the filtration processes and the distillation process. Distillation involves the separation of dissolved solids, in the cow urine; as also the salts (which is a function of the hardness of the solution). These minerals, enzymes, salts and other compounds would be reflected in the

composition of the concentrate; which is a by product after the distillation process.

It is also useful to look at the variance of the admittedly small number of samples - specifically, the standard deviation and the coefficient of variation. The co efficient of variation for the parameter values of the samples for pH, Specific Gravity and water, for both cow urine and CUD seems to be negligible. However for Total Dissolved Solids (TDS) and Hardness, the variance appears to be within tolerable limits for cow urine but high for CUD. Since the numbers involved are relatively miniscule, this does not seem to be a matter of concern. However when specifying the quality control parameters, the ranges would need to be accordingly modified.

A microbiological analysis of the samples seemed to indicate that the following bacteria were absent;

- Escherichia coli
- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella
- Aspergillus niger

Hence it can be stated that the microbiological standards for these bacteria, is that they should be absent from both the cow urine and the CUD.

Table 2: Recommended Standards for Manufacturing Cow Urine Distillate

Parameter	Unit for measurement	Quality standards for cow urine (INPUT)	Quality standards for Cow Urine Distillate (Output)
рН	pH Value	8.00 ± 0.08	9.88± 0.13
Total Dissolved Solids (TDS)	Percentage of total solution(%)	2.37± 0.18	0.47± 0.40
Hardness (in parts per million)	parts per million (ppm)	863± 51	4± 4
Specific Gravity	SG	1.0134±.0007	0.9994±.0005
Water (H ₂ O)(%)	Percentage of total solution(%)	95.38± 0.47	94.79± 0.31
Microbiological Escherichia coli Pseudomonas aeruginosa Staphylococcus aureus Salmonella Aspergillus niger	Bacterial count	Zero	Zero

Summary of the Standards

From the above analysis, the following is stated tentatively as standards for Cow Urine distillation processes for pharmaceutical industries.

Limitations of the study

- The manufacturing standards stated is a "self proclaimed one". These cannot be accepted, till these "probable values" have been experimentally verified by other international scientific bodies.
- 2) The authors are planning to carry out further research on cow urine and cow urine distillate. This could be around the enzymes and other chemical compounds present in raw cow urine and CUD. These need a "bio chemical analysis" - perhaps using High performance Liquid Chromatography (HPLC). These sorts of analysis would perhaps require some "pure science research" - to just ensure that standards are set, for later comparison in HPLC analysis- for cow urine and cow urine distillate. Probably we need to generate a set of standard chromatograms, at different concentrations, to create a calibration curve.
- 3) The third limitation is that application for drugs and other products have not been tested. Some popular products used in Ayurveda medicine, as also consumer products like phenyl can be analysed. This would be "with" and "without" the cow urine/cow urine distillate to prove its value for the drug/consumer product manufacturing industry.

Conclusion

Inspite of the limitations of this study of CUD, there appears to be significant merit in starting the process of standardising the pharmaceutical quality standards for CUD. CUD has definitely started to make inroads

in use as a complementary medicine to mainstream therapies for human health care. It hence perhaps reasonable to conclude, that we should embrace these controversial findings on the therapeutic properties of cow urine; for controversy is the dialectic engine that makes science progress[22]. Pharmaceutical standards for manufacturing Cow Urine Distillate, seems to be the first step in this direction.

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