Brüggemann

„For maximum safety“

Ethanol in GMP and Pharma Quality

Advantages of our GMP Ethanol at a Glance

1.
Foundation

Qualified raw material suppliers for manufacturing GMP Ethanol

2.
Quality Control

Written approval of raw alcohol for the production after comprehensive documentary control through head of quality assurance

3.
Production / Approval

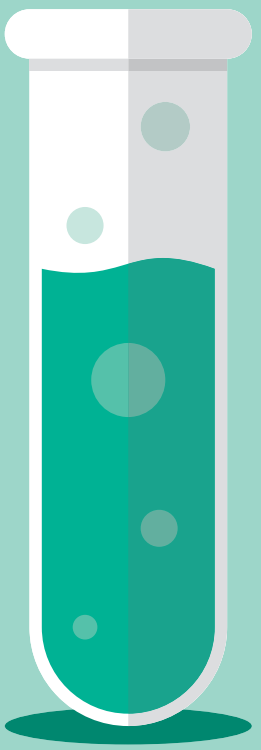
- Dedicated raw alcohol tank is being fully emptied before refilling
- Single-batch production
- All processes for the manufacturing of GMP quality are validated
- All process steps are regulated through SOPs

4.
Filling and Logistics

- Loading of tank truck in closed system (dedicated for GMP)
- Filling of cargo under clean room conditions (overall, hairnet, laminar flow in filling room etc.)
- Label output control process

5.
Additional Documentation

- Batch record for each batch
- Approval for loading through head of quality control



Start Production Process	GMP	Pharma
Raw Material	raw material made from grain, sugar beets and starches from qualified suppliers for GMP production	raw material made from grain, sugar beets and starches from qualified suppliers
Incoming Goods Inspection	according to control plan GMP	according to control plan European Pharmacopoeia
Storage of Raw Alcohol	separate tanks, tank is being emptied before production of active ingredient batches	separate tanks
Tank Inspection	according to control plan GMP, approval after pre-analytics and check of documentation	according to control plan European Pharmacopoeia
Manufacturing Inspections	SOP for manufacturing API quality	work instructions for production
Manufacturing	qualified facilities	qualified facilities
Approval of Intermediate Stages	paper-based with signature, using the dual control principle	digital in SAP R3
Storage of Finished Product	separate tanks, always one manufactured batch, tanks are being emptied before starting active ingredient batch-production	separate tanks, but no complete emptying of the tank when changing batches
Approval of Finished Product	check and release of tank batch through head of quality control, using the dual control principle	check and release of tank batch through head of quality control

	GMP	Pharma
Finished Product Quality	API quality, can be used for the production of excipients and active ingredients	excipient quality
Denaturation (optional)	MEK, 2-Butanone, Eurodenat and further denaturations	MEK and further denaturations
Filling of Tank Truck	filling by closed system, bottom-up	filling by top loader
Filling of Packages	clean room (category ISO 7)	filling room
Hygiene Measures	hygiene clothes in accordance with HACCP guidelines	safety clothes
Empty Packages	from 30l packaging onwards, require batch, according to control plan GMP	do not require batch
Label Output Control Process	yes, according to GMP specifica-tions	no
Batch Record	as pharma, according to SOP for each batch, paper-based	documentation through Excel and SAP R3
Release for Shipment	release of filling batches through head of quality control, using the dual control principle	release of filling batches through head of logistics

Delivery
to Customer

Particularities and Areas of Application of our GMP and Pharma Ethanol

In which areas of application GMP ethanol should be used?

According to §13 (3) of the AMWHV only active ingredients which are produced according to GMP (Good Manufactured Practice) guidelines are approved as starting materials for the manufacturing of pharmaceutical drugs.

Our GMP-certified ethanol offers highest quality standards approved by the German authorities.

In which areas of application pharmaceutical ethanol should be used?

Pharma ethanol complies with the requirements of the European Pharmacopoeia and is thus universally suitable for all pharmaceutical and cosmetic applications for which no GMP certificate is required.

Which pharma monographs meets our GMP and pharma ethanol?

- Ethanol with 96 vol.% complies with the European Pharmacopoeia monograph and due to the harmonization it is also conform to USP (exception: density), BP and JP
- Ethanol with 100 vol.% complies with the European Pharmacopoeia monograph and due to the harmonization it is also conform to USP, BP and JP

What distinguishes GMP from Pharma Europe Quality?

- 100 percent traceability and transparency of manufacturing practice
- Complete documentation of manufacturing practice
- Validated processes
- Four-eye-principle
- Reproducibility
- Inspection by authorities
- Detailed approval process
- Qualified facilities
- GMP quality generally kosher

Why should you buy our GMP Ethanol?

- Fast and flexible delivery
- Short response time
- Personal contact person, short communication channels
- Packaging size from cargo to bulk

Brüggemann

Die entscheidende Verbindung.

Landwirtschaftlicher Ursprung

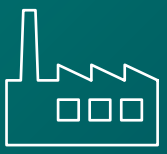
Von der Rohstoffgewinnung bis zum Endprodukt maximale Transparenz

Labor

Sensoriktests und stetige Analysen durch unser qualifiziertes Labor

Lieferung

Zuverlässig und schnell, direkt an Ihren Standort



Zertifizierte Standorte

Heilbronn und Lutherstadt Wittenberg stehen für große Verantwortung, maximale Sicherheit und Flexibilität

Bestellung

Schnell und übersichtlich zu Ihrem gewünschten Produkt über unseren **Produktfinder**

Zuverlässigkeit, Schnelligkeit, Flexibilität, Qualität und Service – das sind die Stärken, die Sie von uns erwarten können!

Mit BrüggemannAlcohol sind Sie stets auf der sicheren Seite! Seit 1868 gehört die Herstellung und Vermarktung von Ethanol zu unseren Kernkompetenzen. Mit unseren beiden Produktionsstätten – Heilbronn und Lutherstadt Wittenberg – ist eine schnelle und flexible Lieferung jederzeit möglich.

Haben wir Ihr Interesse geweckt? Nehmen Sie Kontakt zu uns auf – wir freuen uns auf Sie!

BrüggemannAlcohol Heilbronn GmbH
Salzstraße 129 | 74076 Heilbronn | T +49 7131 1575-0 | F +49 7131 1575-888
alcohol@brueggemann.com | www.brueggemannalcohol.com