



Ethanol in GMP and Pharma Quality

For maximum safety

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

5.

Additional Documentation

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

4.

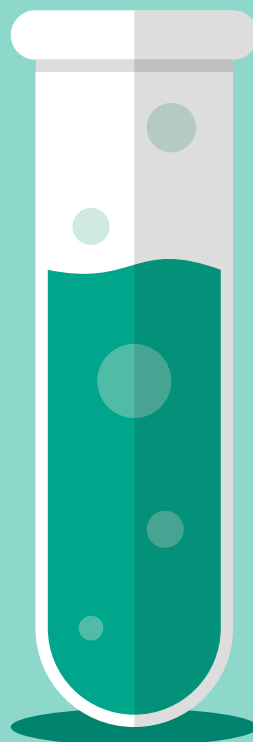
Filling and Logistics

- 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

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





**Start
Production Process**

	GMP	Pharma
Raw Material	raw material out of grain, sugar beets, starches from qualified suppliers	raw material out of grain, sugar beets, 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	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
Approval of Finished Product	check and release of tank batch through head of quality control	check and release of tank batch through head of quality control





	GMP	Pharma
Finished Product Quality	API quality	excipient quality
↓		
Denaturation (optional)	MEK, 2-Butanone	MEK and further individual denaturations
↓		
Filling of Tank Truck	filling by closed system, bottom-up	filling by top loader
↓		
Filling of Packages	clean room (category ISO 8)	filling room
↓		
Hygiene Measures	hygiene clothes	safety clothes
↓		
Empty Packages	from 30l packaging onwards, require batch, according to control plan GMP	do not require batch
↓		
Label Output Control Process	yes	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	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 are the differences between GMP and European Pharmacopoeia?

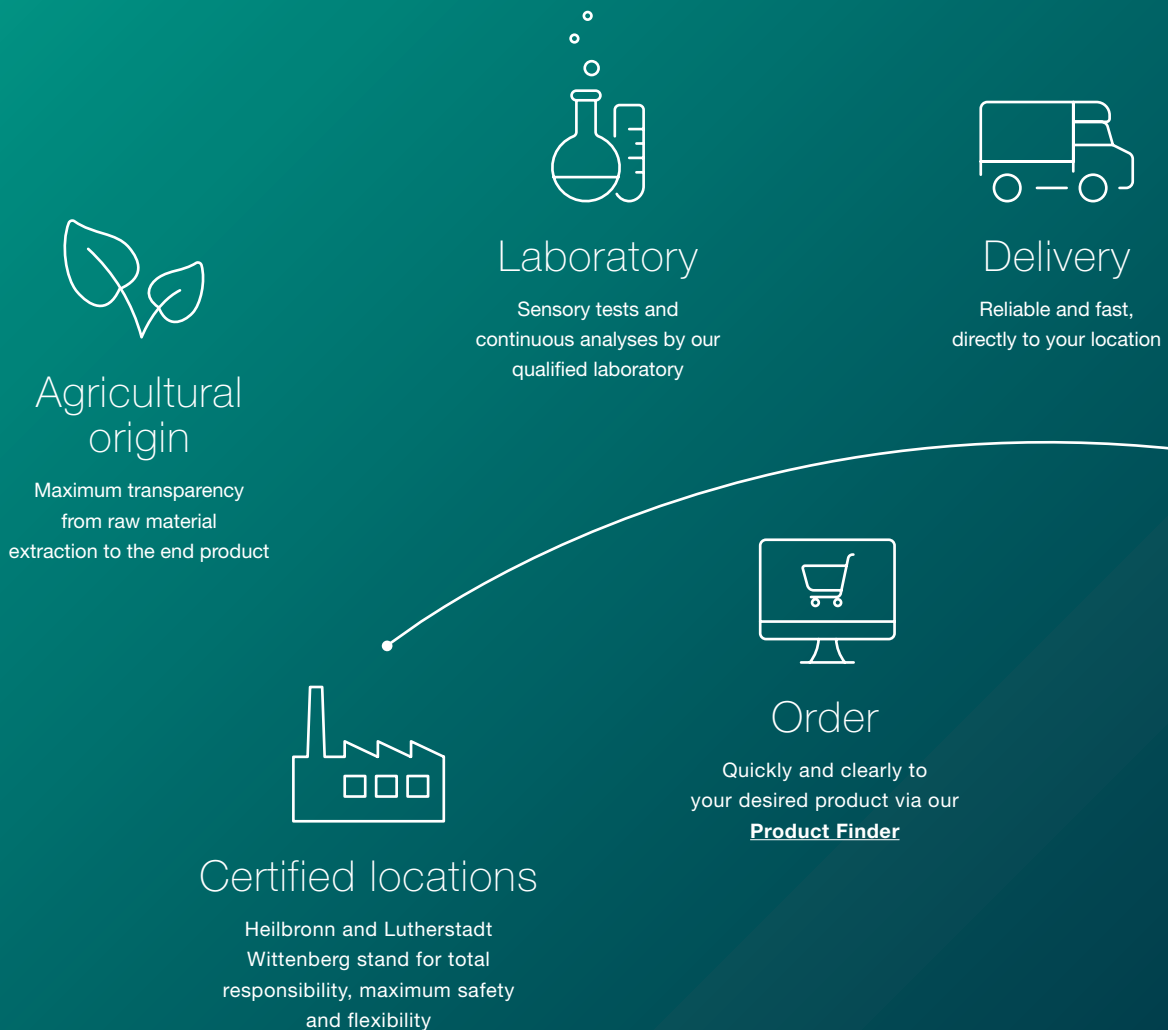
- 100 percent traceability and transparency of manufacturing practice
- Complete documentation of manufacturing practice
- Validated processes
- Four-eye-principle
- Reproducibility
- Inspection by authorities
- Detailed approval process
- Qualified facilities
- GMP quality generally kosher

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



Creating the missing link.



Reliability, speed, flexibility, quality and service –
these are the strengths you can expect from us!

With BrüggemannAlcohol you are always on the safe side! Since 1868, the production and sales of ethanol has been one of our core competencies. With our two production sites – Heilbronn and Lutherstadt Wittenberg – fast and flexible delivery is possible at any time.

Have we caught your interest? Get in touch with us – we look forward to hearing from you!

BrüggemannAlcohol Heilbronn GmbH

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